

# Exhibit V

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

CIVIL ACTION NUMBER:

4 IN RE: VALSARTAN PRODUCTS  
LIABILITY LITIGATION

1:19-md-02875-RBK-JS

**ORAL ARGUMENT ON "MACRO"  
DISCOVERY ISSUES**

Mitchell H. Cohen Building & U.S. Courthouse  
4th & Cooper Streets  
Camden, New Jersey 08101  
Wednesday, November 20, 2019  
Commencing at 10:09 a.m.

BEFORE: THE HONORABLE JOEL SCHNEIDER,  
UNITED STATES MAGISTRATE JUDGE

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25

1 THE DEPUTY CLERK: All rise.

2 (OPEN COURT, November 20, 2019, 10:09 a.m.)

3 THE COURT: Good morning, everybody, please be  
4 seated. Welcome back to Camden.

5 We're on the record in the Valsartan MDL, Docket  
6 No. 19-2875. Whoever is going to speak today, if you could  
7 just state your name. Let's start with plaintiffs.

8 MR. NIGH: Daniel Nigh for the plaintiffs.

9 MR. SLATER: Good morning, Your Honor, Adam Slater  
10 for plaintiffs.

11 MR. HONIK: Good morning, Your Honor, Ruben Honik.

12 MS. WHITELEY: Good morning, Your Honor, Conlee  
13 Whiteley for plaintiffs.

14 MR. PAREKH: Good morning, Your Honor, Behram Parekh  
15 for plaintiffs.

16 MS. GOLDENBERG: Good morning, Marlene Goldenberg for  
17 plaintiffs.

18 MR. WILLIAMSON: George Williamson for plaintiffs.

19 MS. HILTON: Layne Hilton for the plaintiffs.

20 MR. GOLDBERG: Your Honor, Seth Goldberg for ZHP and  
21 the defendants.

22 MR. RUBENSTEIN: Good morning, Your Honor, Brian  
23 Rubenstein for Teva defendants and other defendants.

24 MR. REEFER: Good morning, Your Honor, Jason Reefer  
25 for Mylan and the other defendants.

1                   THE COURT: Okay. This is what we have planned for  
2 today. This morning we'll hear oral argument on all of the,  
3 what I call macro discovery issues that you all have briefed.  
4 If things go according to plan, I'd like to take a relatively  
5 short lunch break and barring unforeseen circumstances, when  
6 you come back from lunch, you'll get rulings on all of the  
7 issues before the Court today.

8                   It's the Court's desire and intent that these rulings  
9 will set the groundwork for your discussions over the next few  
10 weeks, for ultimate resolution on December 11, when we're  
11 dealing with what I call the granular issues, the request for  
12 production of documents.

13                  After the Court reads its rulings into the record,  
14 Judge Kugler is available today, and I thought it would be a  
15 good idea if we meet with Judge Kugler. He's available for  
16 all of you if there's any questions or issues that you'd like  
17 to address with him.

18                  So, if you'll just indulge me, let's get right into  
19 it. I have a few questions, I've read all the papers. I  
20 think I understand the issues. If we could just go through a  
21 couple of questions to get through the background and then  
22 we'll get to the nitty gritty.

23                  Before we get into the issues in the Court's order,  
24 there was one issue I regret not putting into the order that  
25 came to my attention from reading the briefs. I just want to

1 raise it with the parties now. We're not going to decide it  
2 today, and that's the redaction issue. I'd like to hear from  
3 the parties on whether, one, it's appropriate to redact any of  
4 the core discovery that the Court ordered to be produced. I  
5 did not know that that had happened until I read the parties'  
6 briefs, and I'm especially concerned about the redactions  
7 about any correspondence sent to or received from the FDA. I  
8 don't know. I just don't know if it's appropriate.

9 So here's what I'd like to do. We're not going to  
10 decide the issue today. But what I'd like to do is resolve  
11 the issue on December 11th, set a date for simultaneous  
12 briefs. It's not that complicated of an issue.

13 Plaintiff, do you have just a guesstimate of -- are  
14 we talking about a lot of documents, a little number of  
15 documents, do you know?

16 MR. PAREKH: It's a significant number of documents,  
17 Your Honor.

18 THE COURT: Okay. Here's what I'd like you to do.  
19 I'd like you to identify, pick a number, 20 documents, 20  
20 representative documents that you believe should be  
21 unredacted, identify them for the defendant.

22 I'm going to ask plaintiff what their submission to  
23 send the Court copies of what you receive, the unredacted  
24 document, and I'm going to ask the defendants to send -- I'm  
25 sorry, you got the redacted document and I'm going to ask the

1 defendants to send the Court the unredacted documents.

2 Defendants, you pick 20 documents that you think are  
3 representative of the appropriateness of the redactions, send  
4 the Court, of course identify them for the defendant, send the  
5 Court the unredacted copy and the redacted copy.

6 So the Court will have 20 representative documents  
7 from each side. I'm going to review those documents in camera  
8 to see if they should be unredacted, as representative of the  
9 entire scope, and you'll get the Court's ruling on  
10 December 11th.

11 So we're not dealing with a terribly complicated  
12 issue if we get together -- is there any reason -- can we do  
13 simultaneous briefs by December 4?

14 MR. SLATER: Yes.

15 THE COURT: All right. And make sure you identify  
16 fairly promptly the 20 documents you want defendants to  
17 produce to the Court for in-camera review. We'll get all  
18 those documents December 4 with the simultaneous letter briefs  
19 and you'll get the Court's ruling.

20 Plaintiffs, is that the only set of documents that  
21 you're concerned about redactions?

22 MR. PAREKH: Those are the only documents that we  
23 have at this point, so, yes. One point that we would like to  
24 bring up, though, and we've brought this to defendant's  
25 attention multiple times, is that we've never received a

1 privilege log with regards to the redaction documents, which  
2 is required under the ESI protocol and we still haven't.

3 THE COURT: Well, let me suggest this. Let's hold  
4 off on -- it wouldn't be a privilege log, it would be a  
5 redaction log.

6 MR. PAREKH: Redaction log, but it falls under the  
7 privilege log provision of the ESI protocol.

8 THE COURT: So let -- I would suggest you hold off on  
9 that because if the Court rules on December 11 that unredacted  
10 copies have to be produced, then that issue is moot. If the  
11 Court orders that they will stay redacted, then I assume the  
12 parties are going to comply with the agreed-upon Court order  
13 protocol. Okay?

14 I think -- now I remember what I was thinking of.  
15 I'm not sure, it might have been Teva -- it was either Teva or  
16 Mylan, but I think it was Teva, they reproduced redacted  
17 documents but agreed to produce unredacted documents with  
18 their document production. Am I right about that? Do you  
19 remember that?

20 MS. HILTON: Yes, Your Honor. Those represent --  
21 Layne Hilton on behalf of the plaintiffs. Those represent  
22 e-mails that they produced in the course of core discovery  
23 which attached regulatory filings, and the e-mails were from  
24 the custodial file of a regulatory department chair, and they  
25 redacted the internal e-mail, but kept unredacted all of the

1 attachments.

2 THE COURT: But they agreed to produce unredacted  
3 copies.

4 MS. HILTON: Yes.

5 THE COURT: So why in the -- Teva, why in the world  
6 won't you just produce them now? Why do we have to wait?

7 MR. RUBENSTEIN: Your Honor, a point of  
8 clarification. They weren't redacted documents. They were  
9 just withheld. They were strictly internal communications  
10 that were withheld. The communications that went to the FDA  
11 were produced as part of the core discovery. What was  
12 withheld, not redacted, withheld, were the strictly internal  
13 communications within Teva.

14 THE COURT: So the internal communications were not  
15 sent to the FDA.

16 MR. RUBENSTEIN: Correct.

17 THE COURT: So your position is, now it's clarified,  
18 that that wasn't classically within the definition of core  
19 discovery, that's why you held off producing them.

20 MR. RUBENSTEIN: Correct, and we discussed it here  
21 and you agreed with us.

22 THE COURT: Okay. That's a little different than  
23 what was in the papers. So it wasn't redacted, it was just  
24 withheld, right?

25 MS. HILTON: Well, the functional -- if I may, the

1 functional practical implication was that we had an e-mail,  
2 the e-mail had a redaction box and then we had -- you know, we  
3 didn't know that this, you know, other than counsel telling us  
4 that it was an internal communication, but it attached, you  
5 know, 15 correspondences with the FDA, and so we didn't --  
6 our -- functionally, it looked like a redacted document.

7 That's what we saw.

8 THE COURT: Okay. Well, it's clarified now. You'll  
9 get the actual document with the production.

10 MR. SLATER: And, Judge, it ties in with one other  
11 issue we've been bringing up to the Court. We still do not  
12 have all of the documents that are referenced in the core  
13 discovery communications between the manufacturers and the  
14 FDA.

15 For example, they refer to documents that were  
16 provided to the FDA that we do not yet have. It's still --  
17 it's something we've brought up multiple times just to let you  
18 know. We're still waiting for those things and it's going to  
19 come up during the course of the arguments, most likely,  
20 today.

21 THE COURT: These are documents that the Court  
22 already ordered to be produced.

23 MR. SLATER: Right.

24 THE COURT: Has it been brought to the attention what  
25 we're talking about? I haven't seen that anywhere.

1                   MR. SLATER: No. We've mentioned it a couple times,  
2 but we were -- we keep -- we're assuming the defense, because  
3 we've talked to them about it, were going to make sure we had  
4 everything, and we have so much going on, now the rubber is  
5 hitting the road, so they have to complete the production of  
6 everything they gave the FDA.

7                   THE COURT: Is it one company or more than one  
8 company?

9                   MR. SLATER: It's multiple.

10                  THE COURT: All right. Is there a reason why it  
11 hasn't been produced, Mr. Goldberg?

12                  MR. GOLDBERG: Your Honor, assuming I'm understanding  
13 what Mr. Slater is referring to, some of the FDA documents  
14 refer to documents that were made available to the FDA in  
15 China and in India on inspections.

16                  So the FDA documents that we've produced might say,  
17 see Exhibit 7. Exhibit 7 is still in China. It was something  
18 that was reviewed on the inspection, so whether it was in a  
19 room, whether it was in a lab, whether it was in some other  
20 part of the facility, when the FDA is doing their walk-through  
21 in China, there are documents they are looking at.

22                  When we produced our documents in core discovery, I  
23 don't think we had that appreciation, so we produced  
24 everything that we had that we understood to be core  
25 discovery, the FDA communications.

1                   At some point, plaintiffs raised the fact and it was  
2 only recently brought to our attention that there were  
3 exhibits referred to that weren't produced.

4                   We discussed this in a meet and confer on  
5 November 8th, and we told plaintiffs, we will assemble those  
6 documents for you, and we intend to produce those.

7                   I don't know how else to do it. The core discovery  
8 order was talking about readily available documents and  
9 certainly not documents that were someplace else in China.

10                  MR. SLATER: And for obvious reasons, Your Honor, our  
11 view is the order was violated. These documents should have  
12 been produced. They're actually referenced in the documents  
13 that were produced. There could have been no ambiguity on the  
14 Court's order. Whatever they exchanged with the FDA or showed  
15 the FDA should have been produced, and what we keep getting  
16 told is, you have all this core discovery, you're ready to set  
17 search terms and custodianship, that's incomplete. There's  
18 some org charts that are not in our possession yet. There are  
19 some that are not fully translated yet, et cetera.

20                  I just want as a background for the Court's  
21 consideration during the arguments today, to know this, that  
22 we're not armed with everything we're even supposed to have,  
23 which is still a small part of what we ultimately will need.

24                  THE COURT: The documents, Mr. Goldberg, that we're  
25 talking about, is it fair to characterize them as documents

1 that were made available to the FDA for inspection that have  
2 not already been produced?

3 MR. PAREKH: Your Honor, just to clarify, it's our  
4 understanding that during the EIR process, the FDA gets a copy  
5 and takes with it a copy of those documents. They're not just  
6 looked at on-site, but a copy is actually produced and taken  
7 by the FDA, which is why we continue to maintain that those  
8 are communications that were given to the FDA.

9 THE COURT: Did you not receive those documents in  
10 response to your FOIA request? And if not, why not?

11 MS. WHITELEY: Your Honor, this is Conlee Whiteley  
12 speaking. And when we got the establishment inspection  
13 report, it's full of redactions and that's something the FDA  
14 does, but we believe these are documents that would normally  
15 not be redacted under our discovery rules and that we would  
16 want to get from defendants.

17 THE COURT: The redactions we're talking about, if we  
18 step back, I'm talking about the defendant's redactions, not  
19 the FDA's redactions.

20 MR. SLATER: Separate issue, different issue.

21 MS. WHITELEY: That's right, Your Honor.

22 THE COURT: All right. Mr. Goldberg, am I correct,  
23 could we characterize what we're talking about as documents  
24 that were either made available to the FDA for inspection or  
25 produced to the FDA?

1                   MR. GOLDBERG: If they were produced to the FDA, they  
2 were produced to the FDA in China. It's not something that  
3 happened here. And so that's why when we produced the EIR  
4 reports or the 483s or whatever it is that referred to these  
5 documents, we had what we had in the U.S., we produced that.  
6 We were not sensitive to this issue, that there were documents  
7 that were made available by inspection.

8                   THE COURT: So it's in the works.

9                   MR. GOLDBERG: It is in the works, absolutely, yes,  
10 Your Honor.

11                  THE COURT: Is ZHP the only party that this issue  
12 pertains to?

13                  MR. SLATER: No.

14                  THE COURT: Who else does it pertain to?

15                  MS. HILTON: Your Honor, to the extent that any one  
16 was inspected by the FDA, they necessarily provided the FDA  
17 with documentation, and every single EIR produced by every  
18 single defendant to date lists, you know, at the end of the  
19 EIR -- and I'll refer you to Exhibit 1, you can see at the end  
20 of Exhibit 1, you'll see such a list of documentation that is  
21 provided. So every single inspection comes with an exchange  
22 of documents.

23                  THE COURT: All right. So I just made a note about  
24 what we're talking about. Documents that were made available  
25 to the FDA for inspection and/or produced to the FDA during

1       their inspections of defendants', what, API manufacturing  
2 facilities?

3            MR. SLATER: And finished dose.

4            MS. HILTON: And finished dose manufacturing  
5 facilities.

6            THE COURT: Okay. All right. I'll clarify that that  
7 has to be produced. But based on what Mr. Goldberg  
8 represented, it sounds like this is in the works and  
9 plaintiffs are going to get these documents.

10          MR. SLATER: Just, Your Honor, one clarification on  
11 the wording. I can't stand here and tell you the only example  
12 of a document that we don't have that was referenced in a core  
13 discovery document is something that was made available during  
14 inspection. So we just wouldn't want to --

15          THE COURT: Or produced.

16          MR. SLATER: Yeah, I mean it could be during their  
17 correspondence or their back and forth, outside of the  
18 inspections or following the inspections. We just don't want  
19 it to be -- cut out something that may have occurred in the  
20 course of their back and forth.

21          MR. RUBENSTEIN: Your Honor, just a small point of  
22 clarification. During the core discovery process, EIRs,  
23 inspection reports, things like that, were not required to be  
24 produced by the finished dose manufacturers. So it was just  
25 the API manufacturers at this point.

1                   THE COURT: That's one of the issues for today, isn't  
2 it?

3                   MR. RUBENSTEIN: It is.

4                   THE COURT: All right. Okay. So indulge me. I just  
5 have a few questions and we'll get into the nitty gritty.

6                   First, plaintiffs. One of the themes that seems to  
7 be running through defendants' papers is that the die has  
8 already been cast on the cause of this contamination, when it  
9 started. Defendants represent in their briefs that there was  
10 no test to identify these contaminants until July 18, and  
11 based on that, defendants, you know, then go on to their  
12 argument, and I just want to clarify.

13                  If plaintiffs agree to certain prevailing theories,  
14 that's great, that will help us with the scope of discovery,  
15 but I'm not sure that's the case. Can you speak to that?

16                  MR. SLATER: Right. First of all, Your Honor,  
17 there's evidence that we've presented to the Court already on  
18 this briefing that contamination with nitrosamines predated  
19 the manufacturing change to what we're going to call the third  
20 methodology, the one that was the last one they were using --

21                  THE COURT: So are we talking now just about one  
22 party or all API manufacturers?

23                  MR. SLATER: Well, I'm talking -- I'm starting out in  
24 the context of ZHP, because we have more information about  
25 what happened there, of necessity we do. We have evidence

1 that the contamination predated this change.

2                   So we're not at all convinced that this is such a  
3 simple case where, oh, we made a manufacturing change and it  
4 started at that point, because we have evidence that  
5 contamination with nitrosamines predated that date, which is  
6 why the starting point for the effective date, as you're going  
7 to get to, needs to be pushed back to the beginning.

8                   No. 2, the suggestion that no test existed until  
9 after this came to light that could have disclosed it, is -- I  
10 think I learned this word in law school -- silly, because we  
11 know how ZHP found out and how this was discovered, which was  
12 when Novartis looked at their API, which was going to be a  
13 finished dose downstream user of their API and found the  
14 problem and sent it back and said, you have a problem here.

15                  So, you know, that covers a lot of issues. You have  
16 a finished dose where a downstream entity actually discovering  
17 the problem, which shows they actually do things beyond just  
18 cobble it together and shove it into a box, because they have  
19 obligations under the regulatory scheme to look.

20                  So their suggestion that this couldn't have been  
21 discovered makes absolutely no sense. There was testing that  
22 was done, there was so-called ghost peaks being seen for a  
23 long time that were being ignored. We believe that we're  
24 going to be able to show that there was plenty of evidence  
25 that if they didn't actually know it, which there's reason to

1 believe that they did know and kind of just kept going, but  
2 there was certainly plenty of evidence that it could have been  
3 figured out if they just looked at the test results and  
4 actually evaluated them appropriately.

5 THE COURT: So this is my question, and we're not  
6 going to solve the issue of who's right and who's wrong, but I  
7 just want to clarify for the record whether or not a  
8 representation or a statement made by the defendants is  
9 correct.

10 On Page 10 of defendants' November 18th letter, they  
11 say, quote: "And there were simply no testing procedures that  
12 could quantify or detect nitrosamine impurities at such trace  
13 amounts until the FDA introduced new testing procedures in  
14 June 2018."

15 We're not going to -- we can't decide today whether  
16 that's true or not. I just want to know if plaintiffs agree  
17 with that statement.

18 MR. SLATER: No.

19 THE COURT: Okay. And then I understand what the  
20 prevailing theory is about how this contamination occurred.  
21 Later on in the same paragraph that I referred to, the  
22 defendants say: "The purported nitrosamine impurity was  
23 introduced during the API manufacturing process."

24 What are plaintiffs' thoughts about that?

25 MR. SLATER: Oh, we believe that the nitrosamine

1 contamination occurred during the API manufacturing process.  
2 That's what we believe from what we've seen. Whether or not  
3 there also could have been contamination in the finished dose  
4 or downstream facility, we don't have enough information to  
5 prove that, but it's something we obviously have to look at,  
6 because there's obviously going to be cross-claims among the  
7 defendants and we have to see how they're going to handle that  
8 as between one another.

9 THE COURT: Will you be pursuing in the case, whether  
10 or not ultimately you pursue this theory, but at least in  
11 discovery, are you going to explore that there might have been  
12 some contamination introduced into the Valsartan during the  
13 finished dose manufacturing process?

14 MR. SLATER: We're certainly taking discovery on that  
15 and investigating it thoroughly. If it were to turn out that  
16 we have evidence that establishes that, then that would be an  
17 additional basis for liability as to the finished dose  
18 manufacturing.

19 THE COURT: Are you able to rule that out now?

20 MR. SLATER: We're not.

21 THE COURT: Is that one of the reasons why you want  
22 to conduct fulsome discovery directed to the finished dose  
23 manufacturers?

24 MR. SLATER: It's a reason, but it's probably a much  
25 smaller reason than the reason that the finished dose

1 manufacturers have regulatory obligations and had to test, to  
2 audit the API facilities and to be essentially fully  
3 conversant with everything that had happened.

4 For example, take Teva that bought the API from ZHP.  
5 Teva had a regulatory obligation to audit what had happened in  
6 China during the manufacturing process, to look at the test  
7 results, to look at the chromatography, to look at whatever  
8 information -- there's a whole host of things they're supposed  
9 to look at to make sure that they could comply with their good  
10 manufacturing processes obligations.

11 So, you know, they had an independent obligation --  
12 if the API manufacturers weren't involved in this case, the  
13 finished dose manufacturers would be fully responsible for  
14 everything that the API manufacturers did, because they had an  
15 independent obligation to audit and make sure that these were  
16 bioequivalent, that they met the regulations, that they could  
17 comply with all of the generic drug regulations and that they  
18 were safe to be sold, to be ingested by humans in the United  
19 States of America.

20 THE COURT: Did this, in your view, maybe  
21 disagreement on this, did this obligation arise under the  
22 DSCSA, or some other regulatory or statutory authority?

23 MR. SLATER: I think that's part of it.

24 MS. HILTON: Your Honor, if I may, surely we cite to  
25 the drug supply security control act, but they have these

1 obligations under the basic Food & Drug Administration  
2 regulations and because they are the ANDA holders who submit  
3 their Abbreviated New Drug Applications to the FDA, the API is  
4 not obligated to test, but the ANDA holders indeed are.

5 So their obligations actually arise from their  
6 Abbreviated New Drug Applications.

7 MR. HONIK: And at the risk of being old-fashioned,  
8 Judge, the common law imposes a duty as well. I mean, if  
9 Boeing puts an airplane out and there's a defective engine  
10 that's a component part that it got from another party, which  
11 would be roughly equivalent to an API, and puts it into its  
12 plane, it can't raise its hands and say we had no obligation  
13 surrounding that.

14 So in addition to the regulatory scheme, which is as  
15 tight and formative as one could find in any regulated  
16 industry, certainly the common law imposes a duty on the  
17 seller, the finished dose manufacturer, who is incorporating  
18 this component part, that may very well be the rub of this  
19 case.

20 THE COURT: Let me ask one more question of the  
21 plaintiffs and I definitely want to hear from the defendants  
22 on this. I'm not quite sure how to phrase this question, but  
23 I think it's important because so much of the theme running  
24 through defendants' papers is, we should defer to the FDA's  
25 thinking and prevailing theories and if this is what the FDA

1 thinks, why, Judge, are you letting plaintiffs go off on these  
2 alternative theories.

3 How much stock are plaintiffs going to put in the  
4 FDA's findings and prevailing theories?

5 MR. SLATER: The plaintiffs are going to consider  
6 what the FDA found, we're going to consider the information  
7 that they have accumulated through this process and  
8 ultimately, though, we are not going to rely on the FDA's  
9 conclusions for multiple reasons, including the fact that the  
10 FDA, we think, has a part to play in this, because they missed  
11 this, they failed to follow through on some warning letters  
12 and to take some steps against at least ZHP, that probably  
13 should have been taken and we think that the FDA probably has  
14 some incentives to play down the ultimate significance of this  
15 issue. I mean, we could talk about that more another time.

16 So we're going to use the evidence that we're getting  
17 through the FDA. We think a lot of it is very damaging to the  
18 defendants, obviously, because this caused -- I think it's the  
19 largest Class 1 recall ever. So obviously, the FDA wasn't  
20 happy about what happened here and determined these drugs  
21 could not be sold in that form, so we think they've done a lot  
22 to prove our case, but we're going to go well beyond that and  
23 we're going to have to establish in a more granular way the  
24 elements of our case here.

25 MR. HONIK: There's another piece to this as well, if

1 I may, Your Honor. This is an ongoing investigation which,  
2 frankly, has a political component. And what I mean by that  
3 is, that the defendants, through their counsel, have engaged  
4 and continue to engage with the FDA in a very active way.  
5 We're not a part of that, consumers are not a part of that,  
6 buyers are not a part of that.

7 THE COURT: How do you know that?

8 MR. HONIK: Well, because it's in the public domain  
9 and because, as we get FOIA information, we see the contact  
10 between counsel.

11 THE COURT: Shouldn't you be getting -- apart from  
12 FOIA, didn't the Court order that contemporaneous  
13 communications have to be produced?

14 MR. SLATER: Yeah, it's a big problem because we  
15 don't know -- we don't think they're being updated and the --

16 THE COURT: I court-ordered that twice.

17 MR. SLATER: Yes, and Duane Morris, for example, is  
18 the liaison to the FDA on what's -- on this investigation  
19 that's ongoing. So Duane Morris is in, as Mr. Honik just  
20 said, in direct communication with the FDA on this issue. So,  
21 yeah, and we don't believe that we have updated  
22 communications. We think there's probably some significant  
23 gaps, but again, you know, we're not able to say, we don't  
24 have something, we just don't think we have a lot of what's  
25 been exchanged and continues to be.

1 THE COURT: One more question.

2 And I don't know how to put it delicately, but to put  
3 it bluntly, will the plaintiffs be questioning FDA's findings  
4 because they have issues with their potential biases and  
5 motivations in connection with this recall and investigation?

6 MR. SLATER: I would think that there's probably some  
7 conclusions by the FDA that we're going to differ in our  
8 conclusions and our experts will differ, and there may be some  
9 areas that we're going to want to go much deeper into than the  
10 FDA did, because we think there might be some answers there  
11 that they may not want or need, for what they're doing.

12 THE COURT: So, Mr. Goldberg, if you have anything to  
13 say, I don't want to cut you off, I'd like to hear from you on  
14 this. You may not have anything to say, but in light of  
15 plaintiffs' theory of the case, obviously you may disagree  
16 with it, you're entitled to do that. But plaintiffs -- I'm  
17 sorry, defendants argue again on Page 10 of the same letter,  
18 that finished dose testing and anything downstream is simply  
19 irrelevant. That's the defendants' argument.

20 How can you take that position in light of  
21 plaintiffs' theories of the case?

22 MR. GOLDBERG: Your Honor, if I can just sort of back  
23 up and then come to that question.

24 THE COURT: Absolutely.

25 MR. GOLDBERG: Okay. Can I approach, Your Honor,

1 with a couple of documents, please?

2 THE COURT: Sure.

3 MR. GOLDBERG: Your Honor, I think one of the ways  
4 you started this conversation was about the manufacturing  
5 process and whether plaintiffs agree that this is about a  
6 specific part of the manufacturing process.

7 THE COURT: No, what they said was -- if I'm wrong,  
8 they will clarify it, but I think -- my takeaway from what the  
9 plaintiffs said is, yes, they seem to agree with the  
10 prevailing theory that this contamination occurred during the  
11 manufacturing process, but they're not ruling out at this time  
12 that there also may have been contamination caused during the  
13 finished dose manufacturing process.

14 That's how I understood -- they're not saying  
15 exclusively the manufacturing process. That's how I  
16 understood what they were saying.

17 MR. GOLDBERG: I agree with you, that is their theory  
18 that they can't rule out that there was some other  
19 contamination.

20 Your Honor, I've handed you what is the current  
21 manufacturing process for ZHP's Valsartan, and I just think it  
22 would be helpful, we haven't really talked about the science  
23 too much and I'm not an expert in the science and there's  
24 going to be experts here, but, Your Honor, what I've given you  
25 is the multistep process to make Valsartan.

1                   THE COURT: You know, this is exactly why I was a  
2 political science major.

3                   MR. GOLDBERG: Me too, me too.

4                   (Laughter.)

5                   MR. GOLDBERG: But, Your Honor, I just want to show  
6 you, if you turn to the bottom, to Princeton 612, bottom left,  
7 this is Page 7 of 21, this is Step 4 of the multistep process,  
8 and what this -- what I understand from the documents that  
9 I've reviewed, from the different briefs in the case,  
10 including Page 4 of plaintiffs' brief, where they're talking  
11 about a specific moment where solvents are introduced to the  
12 -- to the manufacturing process, that happens right here,  
13 Step 4, where you see it says tetrazole reaction at the top,  
14 it says quenching, and if you look to the left, you'll see  
15 where it says DMF solution in a box.

16                  THE COURT: Yes.

17                  MR. GOLDBERG: Okay. This is -- DMF is the solvent  
18 that's being introduced. This is what's been talked about.  
19 This is the moment, this is the chemical reaction. If there  
20 is one, this is the moment that they're referring to. This is  
21 what this case appears to be about at this point.

22                  Don't -- we don't know exactly what happens, you'll  
23 hear from experts about what happens, but this is really  
24 important to sort of isolate this moment in time, because you  
25 can see all of the steps that happen before, all of the steps

1 that happen after. This is in the moment of creating the  
2 powder at the API facility. This is not the moment of making  
3 a pill at the finished dose facility, putting it in a bottle,  
4 selling it.

5 Plaintiffs may say to you they can't rule it out, but  
6 the logical conclusion is that the contaminations that are  
7 caused -- allegedly caused by DMF, that they've pled in their  
8 case are happening here where the DMF is introduced. That's  
9 the answer to the question. That's their theory. We don't  
10 see how it translates to the finished dose manufacturing  
11 process. No evidence that DMF or any other contaminant is  
12 being put into the drug at that point in time. This is the  
13 process.

14 I wanted to just address the testing question, the  
15 question about whether testing was around at the time to  
16 detect NDMA. I've handed you the FDA's press release, Your  
17 Honor.

18 The second page of the FDA's press release, this is  
19 August -- January 25th, 2019. This says -- Page 4 of 6, which  
20 is in the very bottom, bottom left of the page. During this  
21 time -- this is in the time since the recall, so we're in  
22 January of 2019, we're talking about the last six months.  
23 During this time, our scientists have developed and refined  
24 novel and sophisticated testing methods, specifically designed  
25 to detect and quantify the NDMA and NDEA in all ARB medicines.

1 And then it goes on to describe the three or four tests. At  
2 the time that the recall happened, I don't think we're saying  
3 that there was no ability to identify NDMA. Chromatography  
4 existed. Gas chromatography, liquid chromatography existed.  
5 I think the point is that nobody had their machines at the  
6 sensitivity, nor did the FDA, to detect NDMA and NDEA at the  
7 trace amounts that were found.

8 Did a customer have their machine at the right  
9 sensitivity? Apparently. And so since that time, the FDA and  
10 all of the other manufacturers have been spending their effort  
11 in this investigation to refine the testing, to get it to be  
12 sensitive enough to identify the trace amounts of NDMA and  
13 NDEA in the drug, and that's -- that's the point of what we  
14 said in Page 10. Maybe it wasn't as specific as it should  
15 have been, but that's what we intended by the fact that -- and  
16 that -- and that was the state of the art at the time.

17 MR. REEFER: Excuse me, Your Honor, may I just make  
18 one statement? Judge, I know that --

19 THE COURT: I'm sorry.

20 MR. REEFER: I'm sorry, Jason Reefer for Mylan  
21 Pharmaceuticals.

22 I know that the issue of foreign evidence is going to  
23 come up today, and so with the magic of Google, I tried to  
24 look at some of the foreign regulatory documents that might be  
25 out there, and, you know, this is a statement from the

1 European Medicines Agency, EMA, which in my mind is sort of  
2 like the European FDA, that might not be precisely correct,  
3 but this is a line from an April 17th, 2019, statement that  
4 they made with respect to the nitrosamine impurities and the  
5 recalls.

6 THE COURT: What's the date again, sir?

7 MR. REEFER: Sure. April 17, 2019.

8 It says: "Before June 2018, NDMA and NDEA were not  
9 among the impurities identified in sartan medicines and were  
10 therefore not detected by routine tests." That's the EMA.

11 THE COURT: I don't think that really helps advance  
12 the ball, except to clarify what the Court has to rely on when  
13 it decides the scope of discovery; one, plaintiffs' claims and  
14 your defenses in the case; and two, that's exactly why I asked  
15 Mr. Slater one of the questions, are they deferring to the FDA  
16 and the EMA, and they're clearly not, because they question  
17 their biases and motivations.

18 So the Court has to take that into consideration when  
19 it rules on the scope of discovery. It can't take as gospel  
20 the FDA's statement that this may have been the state of the  
21 art, or what this test was or was not available, because  
22 plaintiffs are challenging those assertions.

23 MR. REEFER: But I don't know that they're  
24 necessarily challenging the assertion that routine testing  
25 would have picked up these impurities at the levels we're

1 seeing.

2 THE COURT: But I don't want to take the wind out of  
3 plaintiffs' sails, but it's no surprise that their --  
4 plaintiffs are going to argue that the routine testing was  
5 wrong, that the defendants knew or should have known that the  
6 routine testing was inadequate. I don't think -- it's no  
7 surprise you're making that argument, plaintiffs, right?

8 MR. SLATER: Not only that, but that the routine  
9 testing, if it was actually evaluated appropriately, would  
10 have led any reasonable person in the defendants' position to  
11 say, we need more information. We're seeing artifacts and  
12 impurities and, quote unquote, their terminology, ghost peaks  
13 on chromatography, that we don't understand why we're seeing  
14 these things, and instead of doing what they did which is  
15 saying, oh, it's just an artifact, we don't have to worry  
16 about and moving on and plowing over it, that they should have  
17 taken a step back because they sit here and say, well, there  
18 wasn't a test to specifically identify a nitrosamine because  
19 they didn't know to look for a nitrosamine, but they certainly  
20 knew to look on the chromatography for the purity and to see  
21 if there were peaks and findings that didn't correlate to what  
22 they expected to see, which under the law, under the  
23 regulatory responsibilities, triggered their obligation to do  
24 more, and they -- and if they had done that, they would have  
25 found out, oh, these are nitrosamines, if they did what they

1 should have done, because again, they sit here and say, nobody  
2 could have found it out, but somebody did find it out, a  
3 downstream purchaser did test it, did find it, did go to ZHP  
4 and say, hey, we're not taking this, you have a problem here  
5 and that's how this entire thing came out.

6 So every time they stand up and say, well, the FDA  
7 says no one could have figured it out, it's absurd, because  
8 somebody else actually did and that's why we know about it.

9 MR. GOLDBERG: Your Honor, I --

10 MR. SLATER: Oh, and the other thing I'll say is  
11 this, just -- I'm sorry, Mr. Goldberg.

12 I thank Mr. Reefer for making a good part of our  
13 argument on foreign regulatory and acknowledging the relevance  
14 of foreign regulatory findings and documents by referring to  
15 the EMA because that is one of the reasons why that it's  
16 relevant, because they've been looking at this question, too,  
17 and there may be communications with those regulatory  
18 authorities different from those with the FDA. That's why we  
19 need all of them.

20 MR. GOLDBERG: Your Honor, I kind of was talk -- the  
21 documents that I've shown you, I don't, I don't think there's  
22 a disagreement about what plaintiffs' theory is, and you're  
23 right, that statement doesn't necessarily advance the ball as  
24 to their theory, should have known, should we have identified  
25 in the test. But what Mr. Slater just did was exactly what we

1 have been trying to do, which is to demonstrate to Your Honor  
2 the narrow issue in the case, which is chromatography testing  
3 about these nitrosamines, about impurities and residual  
4 solvents.

5 That's the theme in our briefing. That's what this  
6 case really is about, and it's really up to the parties and  
7 the Court to figure out, can we stay focused on that issue or  
8 are we going to expand this to something that has, you know,  
9 far more to do with general manufacturing practices, far more  
10 to do with slinging mud about Chinese and Indian companies,  
11 far more to do about different aspects of a manufacturing  
12 process that have no bearing on that moment in time, that  
13 moment in the process where the chemical reaction happens, the  
14 moment that's being investigated by all of these agencies.

15 And if we can't stay focused on that, we're going to  
16 be in a quagmire. We'll be here for years, looking at  
17 hundreds of thousands of millions of pages of documents that  
18 have nothing to do with the chemical reaction that happens at  
19 the moment when DMF is introduced in Step 4 of the process.

20 That's the task at hand here. And to get side -- you  
21 know, go sideways and get sidetracked with so many other  
22 things is -- is going to result in, A, a morass and, B,  
23 exactly what discovery is not intended to do, which is to  
24 somehow raise costs and expense so high that it forces a  
25 settlement.

1                   THE COURT: Okay. I would say in response to one of  
2 the comments you made that testing is -- we're going to deal  
3 with it today, it's certainly a very big issue. I would be  
4 delighted if plaintiffs stand up and say, we agree that the  
5 only relevant test to detect nitrosamines is these chrome --  
6 whatever they are.

7                   MR. GOLDBERG: Sure.

8                   THE COURT: If they agree to that, I would be  
9 delighted, but -- but my instinct tells me that's not going to  
10 happen.

11                  MR. GOLDBERG: And I don't expect them to.

12                  THE COURT: And I don't think -- clearly, they're not  
13 going to get tests, have to do with color and taste and shape  
14 and size. Those issues aren't relevant to the case. They're  
15 not going to get those tests. But suppose they say, you know,  
16 Judge, this type of test could lead someone to identify  
17 whether there's a contaminant of concern in the API or  
18 finished dose.

19                  MR. GOLDBERG: If they come up with that kind of test  
20 and present it to Your Honor, it's a great thing for us to  
21 talk about at that point in time.

22                  THE COURT: Okay.

23                  MR. GOLDBERG: Simply, the theory that some other  
24 test may indicate, without identifying what kind of test that  
25 is, and I think we actually aren't that far apart on testing

1 after hearing their -- reading their brief. I mean, it seems  
2 like the parties are in general agreement about chromatography  
3 testing and bioequivalence, and that does seem to be where we  
4 would want be on testing, and it doesn't seem like there's a  
5 whole lot of dispute there.

6 Now, later in the case, should there be this issue,  
7 how could we say no at that point? But we -- that hasn't been  
8 presented in that way to the Court yet.

9 THE COURT: Okay. We'll get to testing in a few  
10 moments.

11 Another question for the plaintiffs, and it relates  
12 to the one issue I really don't have my arms around yet, and  
13 that's the relevant time for discovery for each of the  
14 defendants. Everything else I think is going to fall into  
15 place and I need your help on it.

16 Plaintiffs -- I'm sorry, defendants. The Court's  
17 understanding is defendants' argument is that only -- the only  
18 Valsartan at issue in this case is the Valsartan that was  
19 recalled. That's defendants' theory. And the follow up to  
20 that is, so since only the recalled Valsartan is at issue,  
21 only the facilities that made the recalled Valsartan are at  
22 issue in the case.

23 What's plaintiffs' thinking on that issue?

24 MR. SLATER: Well, there's a lot of contaminated  
25 Valsartan that people took from lots and batches that were

1 used up before the recalls occurred, No. 1.

2 THE COURT: How do we know that? Why is that the  
3 case?

4 MR. SLATER: Even if we take, for argument's sake,  
5 Mr. Goldberg's theory or ZHP's theory that this started when  
6 they made their change in their process and started to sell  
7 this drug into the U.S., they were selling it to the U.S. for  
8 several years before one of their customers brought to light  
9 that this was a contamination problem with nitrosamine.

10 THE COURT: The change in process was when?

11 MR. SLATER: 2011. Correct?

12 MR. GOLDBERG: December 2013 is when the change was  
13 finalized and approved, Your Honor.

14 MR. SLATER: Oh, you're right. In 2013, they put it  
15 into place.

16 So -- but they were selling into the U.S. for a long  
17 time before this came to light, so there were drugs that were  
18 taken that were -- and those lots and batches, there's no  
19 reason to recall it because it's already been used, and if  
20 they're right, that this is when -- that this process created  
21 the contamination, then it was all contaminated.

22 THE COURT: So let me ask you this question. I'm  
23 sorry for interrupting, Mr. Slater, but if this manufacturing  
24 process, let's say, was put into place online in December '13,  
25 and the contamination wasn't discovered until July 2018, you

1 know, four or five years, plaintiffs' theory is -- is  
2 plaintiffs' theory that all Valsartan made during that time,  
3 using the same manufacturing process, was contaminated?

4 MR. SLATER: Yes, unless they can prove it wasn't,  
5 which is where I've been for months with the defense and with  
6 the Court to say, let's get together and define the entire  
7 field of all Valsartan that was sold in the U.S., let's  
8 identify that which the defendants' agree was contaminated,  
9 let's identify that which they say may have been contaminated,  
10 and let's identify that which they say wasn't, and then we can  
11 really take the defendants at their word and say, now we can  
12 focus a very important issue in the case, because you'll see,  
13 when we ask those questions in core discovery, we got a  
14 gauntlet of objections to -- trying to establish that.

15 But why wouldn't it be all contaminated? They've  
16 just told us, this is the part of their process that caused  
17 the contamination. If they use the same process for every  
18 pill, every pill was subject to the same contamination. That  
19 is -- I don't see how they argue against that and I don't  
20 know, maybe they can make a statement for the Court to try to  
21 narrow issues right now.

22 I would assume they agree, yes, every single  
23 Valsartan pill we sold into the United States, certainly ZHP  
24 will say, yes, it was all contaminated or likely contaminated.

25 MR. HONIK: Your Honor, let me, if I may, to shed

1 some light because you are asking a critical question about  
2 scope, right? What facilities, what products, and temporally,  
3 what are we talking about here.

4 THE COURT: Absolutely critical questions.

5 MR. HONIK: Let me direct your attention to -- this  
6 is a recipe, right? What Mr. Goldberg handed the Court is a  
7 recipe with many, many steps, and he says to the Court, the  
8 only step you need to worry about is on Page 7 of 21, Step 4,  
9 that's when we introduced the DMF solution. Now, we quarrel  
10 with that for the reasons you've already heard. But let me  
11 spin this out so you can understand and hopefully appreciate  
12 the scope and the temporality that we're talking about here.

13 If it's true that the DMF solution is the main  
14 culprit, maybe the sole culprit, then we have to ask  
15 ourselves, when were they starting to introduce this DMF into  
16 their process?

17 THE COURT: Fair question.

18 MR. HONIK: And the answer, Your Honor, is, it began  
19 in Process 1 in 2007, September. That's when they started to  
20 introduce this ingredient into the recipe in their pills.

21 We have already seen, albeit not a lot, but we have  
22 already seen peaks from testing that they've produced to us  
23 that goes back before the timeframe in question.

24 That's DMF in Process 1. They continued to use it in  
25 Process 2, which they submitted to the FDA for approval as

1 early as 2010. The manufacturing change in question was then  
2 subsequently proposed in November of 2011 and as Mr. Goldberg  
3 pointed out, finalized in 2013.

4           Sitting here today, even if we were to agree that the  
5 DMF and its use was somehow the culprit here, we can't say  
6 with absolute certainty without looking back, why did they  
7 choose it, why did they put it in their DMF application to the  
8 FDA? We have to see the thinking process behind their choice  
9 of Step 4 in this recipe, A, to validate whether, in fact,  
10 that's the immaculate conception, I mean, that's the theory  
11 they're coming up with, that you don't have to look at  
12 anything before or after, because it occurred at that split  
13 second.

14           We don't know that. As plaintiffs in court, we  
15 should be permitted to supply to our experts and allow them to  
16 verify whether the theory they're presenting is really true,  
17 if it holds water a little bit or a lot. But the fact that  
18 this step dates back to their own application to the FDA in  
19 2007, implicates their choosing that DMF solution, implicates  
20 the process that they chose.

21           I think this best exemplifies how, at this point in  
22 the litigation, where we haven't really undertaken substantive  
23 discovery beyond the core discovery, that we need to go back  
24 and ask the questions.

25           It's fair to do so, and it's a mistake to think that

1 plaintiffs are simply creating tasks for the defendants to do.  
2 Whatever they produce, we have to look at, on our time, at our  
3 expense, and we're not interested in making work for  
4 ourselves, but we are interested in understanding whether the  
5 recipe theory that Mr. Goldberg has proposed to us, actually  
6 holds water. That's what we want to look at.

7 THE COURT: Let me ask you a question, and I remember  
8 asking these questions at -- if not the first conference, one  
9 of the first conferences. We know that the FDA recalled X  
10 number of lots. Presumably, the reason they recalled those  
11 lots, presumably, I don't know, is because those lots were  
12 tested or a sample of those lots were tested and they were  
13 positive for contamination.

14 Are those all the lots that were made during that  
15 time?

16 MR. SLATER: No.

17 THE COURT: Were there tests done on lots that didn't  
18 detect contamination, and those specific lots were not  
19 recalled? Were some lots -- were some tests positive and some  
20 tests negative?

21 MR. SLATER: I think you have to go defendant by  
22 defendant.

23 THE COURT: Does anybody know that?

24 MR. SLATER: I think you have to go defendant by  
25 defendant and look at the test results, because there's

1 different findings per defendant, and that's again -- what  
2 we're trying to do is to establish what were all the tests  
3 done and I'm sure there's a lot of tests that we don't know  
4 about yet that weren't done as part of the recall, that may or  
5 may not have shown impurities that should have been disclosed,  
6 but all of the pills were not tested, for sure.

7 MR. NIGH: Your Honor, in terms of our understanding,  
8 the FDA directed the defendants to go back and test the pills  
9 that were unexpired at the time that the FDA was -- found out  
10 about this issue.

11 So we even heard Mylan, I believe, Clem months ago  
12 say and agree that that's what they did, they only tested the  
13 unexpired pills. We have reason to believe Mylan has been  
14 selling this since 2012 or 2013. They would have only been  
15 testing back to 2016 because that's when unexpired pills --

16 THE COURT: So hypothetically, I'm just making this  
17 up. Mylan has a hundred lots of unexpired pills.

18 MR. NIGH: Right.

19 THE COURT: I don't even know -- how many pills? No  
20 one ever told us how many pills are in a lot or how many  
21 bottles are in a lot.

22 MR. NIGH: Yes.

23 THE COURT: The recalled lots, was that all 100, or  
24 was it 25 of the 100 lots, and if so, does that mean that some  
25 tests were positive for contamination and some tests

1 weren't --

2 MR. NIGH: Right.

3 THE COURT: -- didn't detect contamination? Do we  
4 know the answer to that?

5 MR. NIGH: We don't. We have an incomplete set of  
6 testing from my eyes, and from our risk assessment expert  
7 looking at it, says, we're missing a lot of pieces to what we  
8 would want for testing. It would be not only important to see  
9 the testing for what hits is a contamination for over 96  
10 nanograms, but it would also be important to understand all  
11 the testing for the not detected nanograms in that same lot,  
12 and that's what we -- we don't have a full picture on the  
13 testing.

14 THE COURT: Do we know how the FDA determined that  
15 certain lots were going to be recalled and certain lots were  
16 not going to be recalled, and the identity of the not recalled  
17 lots, and hypothetically, because I don't know, suppose  
18 there's a hundred lots, 25 were recalled, what does that do to  
19 the theory that every pill or all API made during that time  
20 period was contaminated, if there were 75 of a hundred lots  
21 that were not recalled?

22 MR. NIGH: Yeah, and I think this is a defendant by  
23 defendant issue. ZHP, my understanding, they've come out,  
24 they've expressed that every Valsartan pill that made its way  
25 into the U.S. was over -- was heavily contaminated over the 96

1 nanograms. The other defendants would have been -- the  
2 direction, my understanding is the FDA looked to the other  
3 defendants and said, test your unexpired pills for each lot,  
4 come up with a protocol as to -- but if it's over 96  
5 nanograms, we need to issue a recall of that lot.

6 So we were still going to have contamination even  
7 under 96 nanograms for unrecalled lots in the unexpired.

8 THE COURT: Do you have all the test results -- once  
9 the contamination was discovered, and the FDA directed that  
10 testing be done in order to identify what had to be recalled  
11 or not, do you have all of those test results?

12 MR. NIGH: No, no. I mean, one example would be --  
13 I'm certain we don't have all the testing results for Teva.  
14 You know, Teva is -- they have the combination that has a  
15 lower level of contamination and they have just Valsartan that  
16 clearly has their higher level of contamination. We don't  
17 have that testing for the higher level. So that's just one  
18 example.

19 THE COURT: Is there anything you want to add on  
20 this, Mr. Goldberg?

21 MR. GOLDBERG: I guess a couple of points to clarify.  
22 One thing to clarify with respect to ZHP, and going back as  
23 Mr. Honik was saying. The only ZHP pills that have been sold  
24 in the U.S., APIs sold into the U.S., only happened after  
25 2015, when we -- when ANDA filers using our API were approved.

1                   So we were manufacturing product prior to 2013 using  
2 a different process, and if Mr. Honik is correct that DMF was  
3 used during that process, so be it.

4                   Drugs made from that process were not sold into the  
5 U.S., which is why in our briefing, we tried to draw a line  
6 with respect to the relevant time period as it relates to ZHP  
7 and I think probably as to some of the other defendants.

8                   THE COURT: Do I take it then ZHP was selling API  
9 around the world before 2015 but only as to the United States  
10 after 2015?

11                  MR. GOLDBERG: I believe that's correct. I'm not  
12 sure which countries around the world. I know in China they  
13 were, but I'm not sure which, but for U.S. sales of ZHP API,  
14 it only occurred after 2015 -- since 2015, and we provided  
15 that information to plaintiffs, our letters of authorization  
16 are in the document.

17                  So our thinking on relevant time period is, and it  
18 does go back to this. I don't know that it's a recipe, and  
19 I'm not suggesting that this one moment in time is the only  
20 relevant part of the process, but what I am suggesting is that  
21 this is -- you know, this is the most important part that  
22 should really guide how we look at discovery.

23                  The -- sorry, I lost my train of thought, about the  
24 -- oh, I think what I would -- what we are suggesting about  
25 this process, with respect to relevant time period is, to the

1 extent there are specific questions about the process that  
2 predate 2015, then let's focus on those, but certainly general  
3 discovery as to all of these other topics in the 122-some-odd  
4 requests don't need to go back that far, and that a cut is  
5 2015, and then, you know, if there are specific questions,  
6 specific questions about residual solvents, impurities, this  
7 step in the process, some other key step, then raise it that  
8 way, and so that we're not mired down in a morass of documents  
9 that date back into, not only more than a dozen years as to  
10 some defendants, but also with respect to processes and pills  
11 that are not at issue in the U.S.

12 MR. NIGH: Your Honor, if I can clarify a few things.  
13 For ZHP, they have three different processes as to how they  
14 make their Valsartan from what we understand. They've got a  
15 TEN process, it's called Process 1. They have a TEA process  
16 called Process 2, and then a DMF Process 2. Those are the  
17 three different types of processes. So the recipe that was  
18 shown is DMF Process 2.

19 The problem with what we just -- and the Chinese --  
20 ZHP alerted the FDA, they said, this is the reason for their  
21 problem, it's Process 2 DMF, and we're hearing it again that  
22 we should limit it to just DMF Process 2. That's the issue.

23 But the problem is, we've submitted a Claussen  
24 report, 58-page inspection report from Claussen in 2018. She  
25 asked Jun Du and asked, well, did you test, did you get

1 testing results on the other processes, and they again said,  
2 there's no problem with the other processes, but the FDA said,  
3 but did you test them.

4 Well, guess what happens? The day before the  
5 inspection concludes, they come back and they reveal, there  
6 are very high levels for TEA Process 2, so now it's not just  
7 Process 2 DMF, it's also Process 2 TEA, that we don't know  
8 even utilizes DMF. So I don't think that we can just define  
9 this and say, that's the only problem that we know about, and  
10 also to say that Process 2 DMF is the only one that makes its  
11 way to the United States.

12 I don't believe that's accurate, but I'm not certain,  
13 but I don't believe that's accurate. I believe it's being  
14 sold to Torrent and it makes its way into the United States.

15 So that's another reason why we need to find this  
16 out. We would then need to understand, if all that's  
17 accurate, we would need to understand why is it, if Process 1  
18 doesn't have a high impurity finding, but Process 2 TEA does  
19 and Process 2 DMF does, that could be our answer. That's why  
20 we would need discovery into all three of the processes for  
21 ZHP.

22 THE COURT: Okay. Real quickly, couple of questions.

23 Are you going to orally argue the motion in December  
24 before the JPML panel?

25 MR. NIGH: I am not, because they are not asking for

1 oral argument.

2 THE COURT: Okay. Am I correct that Hetero Aurobindo  
3 India, they haven't been served yet? Is their counsel here  
4 for the U.S. entity?

5 MS. POLETO: I am here, Your Honor.

6 MS. HEINZ: Yes, Your Honor.

7 THE COURT: They know -- you don't have to answer  
8 this. The train has left the station. When they eventually  
9 come into this case, they're going to have a lot of catching  
10 up to do quickly, because they're on notice of everything  
11 that's been going on in the case, so they had the opportunity  
12 -- they're exercising their right, perfectly appropriate, no  
13 problem with it.

14 But if they think they're going to come into this  
15 case and we're going to start at ground zero, they're  
16 mistaken. That's the only thing I wanted to say. You don't  
17 have to respond, but I just want to make sure they know that  
18 the train has left the station. Okay?

19 MS. POLETO: Duly noted, Your Honor.

20 MS. HILTON: And, Your Honor, if I may, Hetero Drugs  
21 did receive a Complaint in India. Counsel for Hetero USA  
22 forwarded it to me. It was one of the Longwell class  
23 Complaint and was filed in the District Massachusetts --  
24 Hetero Drugs in India received a copy of our Complaint, we  
25 received a copy of it from counsel for Hetero USA and it

1 included the Indian certificate on the front and it was -- it  
2 was one of our Massachusetts class complaints, and so they are  
3 in receipt of the Complaint, but we just have not received --  
4 I personally have not received a signed certificate back from  
5 India which takes, you know, a month or two months.

6 THE COURT: Once the two companies are properly  
7 served pursuant to the Hague or at least you get evidence of  
8 that, do you know how long they have to respond to the --  
9 well, no answers have been filed, so I guess what I'm asking  
10 is, how long after they're served, do they enter an  
11 appearance?

12 Or let me put it this way. As soon as -- will you be  
13 the person who gets notice that the two companies have been  
14 properly served pursuant to the Hague?

15 MS. HILTON: I believe I'll get some sort of  
16 documentation from India. I don't know what that looks like.

17 THE COURT: All right. The Court wants to know  
18 immediately, because we will order that an entry of appearance  
19 be entered, and if we have to, we'll enter an order saying  
20 those specific parties have to file answers to the Complaint,  
21 and if they don't, there's going to be a default, because I  
22 don't want any undue delay after they're served while they  
23 wait and finally get around to entering an appearance.

24 I want them in the case as soon as they're properly  
25 served. So let us know when that happens. Okay?

1           We're not going to grant undue extensions of time to  
2 enter an appearance or file this or file that, clerk's order,  
3 blah, blah, blah. Those days are over. Okay?

4           One more question and then we'll get to the specific  
5 issues that we have to deal with.

6           Teva's counsel.

7           MR. RUBENSTEIN: Yes, Your Honor.

8           THE COURT: I'm not quite understanding this Malta  
9 facility issue. If it's just a question of whether they fit  
10 into the category of facility that has to respond to  
11 discovery, that's fine, we'll deal with this, but do we have a  
12 successor liability issue that has to be addressed in the  
13 first instance before we get to that?

14           MR. RUBENSTEIN: No, I don't know, there is no issue.  
15 Teva is not going to be withholding documents from Malta.  
16 Malta was one of the manufacturing facilities that made  
17 Valsartan for sale in the United States.

18           Teva will be producing documents regarding the  
19 manufacture, you know, the process and everything, the testing  
20 that was done there. Teva will be producing those documents,  
21 so there is no that I, you know, issue with the Malta  
22 facility.

23           THE COURT: Okay. So there will be --

24           MR. RUBENSTEIN: It doesn't exist anymore as a legal  
25 entity.

1                   THE COURT: We don't have to deal with the successor  
2 liability.

3                   MR. RUBENSTEIN: No.

4                   THE COURT: Okay. Let's -- now I'm ready to -- or  
5 the Court is ready to get to the specific issues in the  
6 dispute, and in looking at it, it made sense to me to start  
7 with the issues that plaintiffs started on, and then we'll go  
8 to defendants, and I suggest we just go down the order -- in  
9 the order.

10                  The first issue is what the Court called boilerplate  
11 objections. The Court -- that's the only issue the Court  
12 doesn't need oral argument on.

13                  I read the briefs, read the papers. I understand  
14 everything. I don't think you can add anything to the record.

15                  So let's move on to issue No. 2. What entities or  
16 facilities must respond to plaintiffs' discovery. Pretty  
17 important issue.

18                  Let me ask you this: Do we at least know how many  
19 facilities and what the facilities are that we're talking  
20 about?

21                  MS. HILTON: Well, all of the facilities, if I may,  
22 Your Honor, all of the facilities that are used in the  
23 manufacture of finished pills that enter the U.S. market  
24 pursuant to --

25                  THE COURT: Let's start with the API.

1 MS. HILTON: We know which facilities were used that  
2 manufacture, and you'll note that defendants were very clear  
3 in their language. Valsartan API, that was subject to recall.  
4 This leads me to believe that there are, perhaps, facilities  
5 they have not identified.

6 THE COURT: Well, that's the question. That's the  
7 question I asked. Do we know at least the universe of  
8 facilities that made API as a starting point and then we can  
9 identify the facilities that had recalled API, the facilities  
10 that sold U.S. API and the facilities that only sold foreign  
11 API. Do we know that?

12 MS. HILTON: No, Your Honor, we don't. We only know  
13 which facilities manufactured API that was subject to a  
14 recall. That is what defendants have given us. We know the  
15 universe of facilities that defendants have generally, but it  
16 is possible that some facility or some process may make API,  
17 and in another facility may make finished dose. They have  
18 just been very clear that they are only providing us with --

19 THE COURT: Let's just start with it -- first, we're  
20 going to start with API. That's different from finished dose.  
21 Are they separate facilities?

22 MS. HILTON: Based on my understanding, sometimes  
23 they are not.

24 THE COURT: Okay. So defendants say, we want to  
25 limit the facilities at issue to only those that sold the

1 recalled API. Do we know right now whether or not that's the  
2 universe of all API facilities?

3 MS. HILTON: We don't know that, and we have reason  
4 to believe that it's not the universe of all API facilities.

5 THE COURT: So what facilities do you think should be  
6 at issue in the case?

7 MS. HILTON: We believe any facility that  
8 manufactured Valsartan API should be subject to discovery.

9 THE COURT: Suppose I don't know, we don't know -- I  
10 wish we had the answers to these questions. Suppose there's  
11 an API facility that only made APIs sold to Belgium and  
12 France, obviously I'm making this up, they didn't sell any API  
13 that entered into the United States. Is it your position that  
14 discovery as to that facility is relevant?

15 MS. HILTON: Yes, Your Honor.

16 THE COURT: Why?

17 MS. HILTON: We understand that the defendants  
18 utilized different manufacturing processes, recipes as it  
19 were, for different countries, based on different guidelines  
20 and requirements those countries had.

21 So to the extent Belgium had no adulterated  
22 contaminated Valsartan with nitrosamines, we would be  
23 interested in seeing what those testing results look like,  
24 what those documents look like and whether, you know, because  
25 another Valsartan was showing aberrant peaks, the defendants

1 should have been on notice. If there was a country that had  
2 an adulteration or contamination that was at even higher  
3 levels than the United States, you know, we would want to see  
4 that testing so we could compare.

5 THE COURT: Mr. Goldberg, isn't it just a basic,  
6 basic, basic fact to identify the universe of potential  
7 facilities at issue?

8 MR. GOLDBERG: Yeah, I'm not sure -- I'm not sure  
9 they haven't been, Your Honor.

10 THE COURT: Okay, so --

11 MR. GOLDBERG: I know for ZHP, plaintiffs know where  
12 the stuff is made.

13 THE COURT: Okay. Just as -- I'll ask the other  
14 party, just ZHP. ZHP wants -- as well as the other API  
15 people, want to limit the facilities at issue to only the  
16 facilities that made the recalled API, right?

17 MR. GOLDBERG: Well, for us, that's our Valsartan.

18 THE COURT: So as to --

19 MR. GOLDBERG: We voluntarily recalled everything  
20 that came to the U.S.

21 THE COURT: So it's all of your API manufacturing  
22 facilities?

23 MR. SLATER: We have Chuannan and we have Xunqiao.  
24 And Chuannan is where the API is made. Xunqiao -- Chuannan  
25 has two -- we have two zones and Xunqiao, I believe, is where

1 the finished dose is made, and we have said they can have  
2 discovery as to both.

3 THE COURT: Okay. So it's easy with regard to your  
4 client.

5 MR. GOLDBERG: Correct.

6 THE COURT: Mylan?

7 MR. REEFER: Hi, Judge. Yeah, Mylan has identified  
8 all of the facilities that have manufactured Valsartan API,  
9 they're referred to as Unit 8 and Unit 3 and we've provided  
10 their identification information.

11 THE COURT: Did they both sell recalled API?

12 MR. REEFER: I believe so, Judge.

13 THE COURT: So we don't have an issue -- well, are  
14 those the only two facilities that made API for your client?

15 MR. REEFER: Valsartan API, yes, Judge.

16 THE COURT: So we don't -- so far we don't have an  
17 issue with ZHP, we don't have an issue with Mylan.

18 MS. HILTON: Your Honor, if I may. I mean, could we  
19 get confirmation that they're not limiting it to just the  
20 United States and that they are answering with respect to all  
21 of their processes around the world, because --

22 THE COURT: They just said that they only have -- you  
23 have two facilities, you have three facilities, right?

24 Do you have any -- all right.

25 Mylan, do you have any API manufacturing facilities

1 that exclusively sells to non U.S. customers?

2 MR. REEFER: No, Judge.

3 THE COURT: ZHP?

4 MR. GOLDBERG: No, Your Honor.

5 THE COURT: So right now, Mylan and ZHP are the only  
6 API manufacturers in the case, right? Because Hetero and  
7 Aurobindo are not in the case yet, right? Okay.

8 MR. GOLDBERG: I believe that's correct.

9 THE COURT: So we don't really have -- well, that's  
10 API. Let's go to finished dose.

11 MS. HILTON: Yes, Your Honor. So the defendants --  
12 first of all, I think Mr. Rubenstein said earlier that they  
13 did not produce establishment inspection reports in core  
14 discovery. That's actually not correct. The finished dose  
15 manufacturers did. I looked at some last night. So I know  
16 that some of the finished dose facilities, Aurolife, for  
17 example, did produce establishment inspection reports.

18 And so we know, we believe that we are entitled to  
19 discover especially quality assurance-related documents.

20 THE COURT: No, no, no, let's not move on to the next  
21 issue. We're just talking first --

22 MS. HILTON: Oh, identification.

23 THE COURT: Right. First, we're going to identify  
24 the facilities at issue, and then we'll get into the specific  
25 documents.

1                   So I take it, you want the defendants to produce  
2 responsive discovery for all finished dose manufacturing  
3 facilities, not just those that sold recalled products?

4                   MS. HILTON: Yes, Your Honor.

5                   THE COURT: Okay. We don't have an issue with ZHP,  
6 Mr. Goldberg, as I understand it, right?

7                   MR. GOLDBERG: Correct, to the extent we're going to  
8 produce finished dose manufacturing-related documents, they're  
9 at Xunqiao and that's the one.

10                  THE COURT: Right. So Mylan, do you have finished --  
11 separate finished dose manufacturing facilities?

12                  MR. REEFER: Yes, Judge. Nashik in India.

13                  THE COURT: Is this apart from the three API  
14 facilities?

15                  MR. REEFER: To clarify, Judge, we have two API  
16 facilities, one's called Unit 3. It no longer manufactures  
17 Valsartan API as of, I believe, 2017. Presently, the only  
18 Valsartan API manufactured by Mylan is done at Unit 8 which  
19 again has also been identified.

20                  Separately, we have finished dose facilities in  
21 Nashik, India, and Morgantown, West Virginia.

22                  THE COURT: Did both of those facilities sell  
23 recalled finished dose products?

24                  MR. REEFER: Yes, I believe so, Judge.

25                  THE COURT: Okay. So we don't have an issue with

1 Mylan.

2 MS. HILTON: So we have several issues with Mylan but  
3 in terms of identification --

4 THE COURT: Of their facilities.

5 MS. HILTON: -- of their facilities.

6 THE COURT: One step at a time.

7 MS. HILTON: Yes, Your Honor.

8 THE COURT: Teva, your finished dose manufacturing  
9 facilities are located where?

10 MR. RUBENSTEIN: In Jerusalem and Malta.

11 THE COURT: Did both of those sell -- well, I'm not  
12 sure about Malta. Did both of those sell recalled Valsartan?

13 MR. RUBENSTEIN: Yes. They're the only two  
14 facilities that manufactured Valsartan for sale in the United  
15 States, whether they were recalled or not.

16 THE COURT: Is there a -- I know we're going to get  
17 into specifically what documents, each of facilities has to  
18 produce, but is there a dispute that documents are going to be  
19 produced from both of those facilities?

20 MR. RUBENSTEIN: No.

21 THE COURT: Torrent. Your finished dose  
22 manufacturing facility is located in India?

23 MS. NAGLE, correct.

24 THE COURT: Is there only one?

25 MS. NAGLE: Yes.

1 THE COURT: Did they sell recalled product?

2 MS. NAGLE: Yes.

3 THE COURT: Okay. So we don't -- we don't have any  
4 dispute anymore because all API -- API manufacturing  
5 facilities and all finished dose manufacturing facilities of  
6 the defendants sold recalled product, so we don't have an  
7 issue so far.

8 MR. SLATER: Your Honor, I may have missed it. But  
9 on Teva, what we were told is those were the facilities that  
10 sold to the U.S., I think we just lost the one piece. Did  
11 they have facilities that manufactured Valsartan for sale in  
12 other countries solely and not in the U.S.?

13 MR. RUBENSTEIN: Yes, they have other facilities.

14 MR. SLATER: So we're looking for discovery from  
15 those facilities as well. So we need to make sure we have  
16 those. I don't know that we do.

17 THE COURT: Okay. That was -- I'm sorry, Teva.

18 MR. RUBENSTEIN: Correct.

19 THE COURT: The two facilities that sold recalled  
20 product, they're located where?

21 MR. RUBENSTEIN: In Jerusalem and formerly in Malta.

22 THE COURT: And the finished dose facilities that  
23 sold only to non-U.S. customers, that's located where?

24 MR. RUBENSTEIN: There are multiple. I don't know  
25 off the top of my head.

1                   THE COURT: Okay. So plaintiffs' position is all of  
2 the facilities, whether or not they sold recalled product,  
3 have to be subject to discovery.

4                   Defendants' position is, it's only -- really only  
5 pertaining to your client, that the facilities that didn't  
6 sell recalled product should not be subject to discovery.

7                   MR. RUBENSTEIN: That didn't -- that didn't  
8 manufacture product for sale in the United States. Whether it  
9 was recalled or not.

10                  So if a facility that may have manufactured Valsartan  
11 solely for sale outside the United States should not be  
12 subject to discovery, but the two facilities, Jerusalem  
13 formerly Malta manufactured Valsartan that was for sale,  
14 they're the only two facilities that manufactured Valsartan,  
15 finished dose products for sale in the United States.

16                  THE COURT: Okay. The issue is joined. I understand  
17 the issue, I understand the arguments. Yes, Mr. Slater.

18                  MR. SLATER: There's just one thing Your Honor needs  
19 to be aware of. It may be that a Teva facility may have sold  
20 solely to a non-U.S. market, but that someone in that non-U.S.  
21 market may have then repackaged and sold it into the U.S.,  
22 so --

23                  MR. RUBENSTEIN: That's not my understanding.

24                  MR. SLATER: We just want to make sure we don't miss  
25 something because our understanding was some foreign entities

1 may have purchased the drug from -- higher in the stream of  
2 supply, and then directed it into the U.S. We just want to  
3 make sure we don't miss something like that.

4 THE COURT: Are most, for the finished dose  
5 manufacturers, is the stream of commerce, if they're going to  
6 sell the finished dose pill, would it go directly to the  
7 United States or would it go through somebody else to the  
8 United States?

9 MR. RUBENSTEIN: My understanding is that it goes  
10 through the -- directly through the United States.

11 THE COURT: Is that the same for Mylan and ZHP?

12 MR. REEFER: Your Honor, with respect to Morgantown,  
13 it is in the United States so --

14 THE COURT: That's easy.

15 MR. REEFER: That's the easy one. With respect to  
16 the Nashik facility, my understanding is it is distributed  
17 through Mylan Pharmaceuticals, Inc., which is a West Virginia  
18 entity that operates the Morgantown plant as well.

19 THE COURT: Correct.

20 MR. REEFER: So does that -- I think that's answering  
21 the question.

22 MR. GOLDBERG: And for ZHP, Your Honor, the finished  
23 dose that we make in China comes straight from our distributor  
24 in the U.S.

25 THE COURT: Okay. All right. That issue is joined

1 and we'll address that probably right after lunch.

2                   Third issue, whether defendants should be required to  
3 identify and produce discovery regarding other products using  
4 the same manufacturing processes, solvents and/or testing as  
5 those for Valsartan API, plaintiffs in effect are requesting  
6 to open up discovery as to -- I take it all sartans and all  
7 processes that use, what, DMF?

8                   MR. SLATER: I don't think limited to the DMF  
9 process, because there's a prior process as well.

10                  THE COURT: Okay. That's a pretty big expansion,  
11 plaintiffs. Why do we need that?

12                  MR. STANOCH: Hi, Your Honor. David Stanoch for  
13 plaintiff. Judge, we know that certain sartans have the same  
14 chemical structure, right, that's the same Step 4 -- step  
15 we've seen on the ingredient list, that same thing is  
16 happening with the other sartans. We know that they're  
17 manufactured the same or substantially similar way, using the  
18 same or similar solvents, and that the testing results for the  
19 carcinogenic -- the impurities that we know from the recalls  
20 that's been found, at least some of these other drugs.

21                  For the same reasons we were talking about earlier,  
22 if we're -- if we're detecting NDMA in losartan, that's a  
23 flag, that's a signal, that's a notice that it may be  
24 occurring in the same process, using the same solvents for the  
25 same chemical step for Valsartan.

1                   THE COURT: Is there any evidence, any evidence, that  
2 any contamination was discovered in any sartan before  
3 July '18?

4                   MR. STANOCH: I'm not personally aware of that,  
5 Judge.

6                   THE COURT: I mean, plaintiffs are arguing they  
7 should have been aware of it, I know that.

8                   MR. STANOCH: Correction, Judge, there were, of  
9 course, ghost peaks and other types of signals which we  
10 believe, at least from the limited discovery we have gotten so  
11 far, which should suggest that, that there was something there  
12 or at least further investigation should have happened.

13                  THE COURT: So if you get discovery with regard to  
14 Valsartan, why then do you need all these other sartans?

15                  MR. STANOCH: Well, again, again, Judge, we're not --  
16 we don't want full discovery of every single thing about  
17 losartan, we're not saying losartan for example, is a search  
18 term, we're saying to the extent the manufacturing process in  
19 solvents were being used, which ones are being used for both  
20 processes, and if they were different and yielding different  
21 results, that's going to go to the knowledge and notice of the  
22 defendants.

23                  THE COURT: So hypothetically, if you had a wish list  
24 of what you could find, what would you hope exists that you're  
25 not going to get through the Valsartan discovery?

1 MR. STANOCH: Well, it could be, hypothetically, you  
2 know, one of two things. Let's say, you know, we know for  
3 example, at some point ZHP was using a recycled solvent which  
4 some have suggested, one of multiple hypotheses, that the  
5 solvent itself might be the source of the contamination.

6 For example, we submitted with our briefing a 2019  
7 statement about Lantech that was supplying the solvent where  
8 it was said that the solvent was what contained the NDMA. If  
9 they're doing the same process, with a different solvent for  
10 losartan and they're not finding that problem, then we know  
11 there's probably the problem on the Valsartan side. If  
12 they're using different solvents, right?

13 THE COURT: Last question. When -- again, not to  
14 take the wind out of his hand -- out of his sails, but I  
15 expect to hear from the defendants that these other products  
16 are not at issue in the case, these other processes are not at  
17 issue in the case. You're going to get, plaintiffs are going  
18 to get extensive Valsartan discovery.

19 The discovery that plaintiffs are requesting as to  
20 this issue is disproportional to its importance in the case.  
21 It's cumulative, duplicative, what have you.

**22** How do you respond to that?

23                   MR. STANOCH: I'd say that the defendants have not  
24 made a particularized showing of what that burden may be at  
25 this stage, Your Honor.

1           They're probably using the same or similar testing,  
2 using the same or similar machines, kept in the same or  
3 similar database, with the same or similar results.

4           We have had no showing that it's going to be some  
5 humongous process to go to a different facility with different  
6 custodians, different chromatogram machines, and different  
7 data extraction. It's all probably going to be on the same  
8 thing because they're all going to be coming off the same  
9 facility line using the same chromatography machine, going  
10 into the same computer.

11           They can just hit -- I know it's a simplification.  
12 I've been on that side myself, but the point is, it's going to  
13 be all in one place. And if you're queuing the data and you  
14 have to say Code 1 Valsartan, it's not burdensome to say also  
15 Codes 2 and 3, losartan, irbesartan.

16           THE COURT: Thank you. Mr. Goldberg, do you want to  
17 be heard?

18           MR. GOLDBERG: Thank you, Your Honor. I think Your  
19 Honor took the wind out of my sails.

20           THE COURT: Did I take the wind out of your sails?  
21 Excuse me for that, Mr. Goldberg.

22           MR. GOLDBERG: And obviously, this is an obvious  
23 significant expansion to this case. We do have the JPML  
24 motion and the JPML hasn't decided whether these drugs are  
25 even in this MDL. Obviously, discovery looks different as to

1 these drugs. If it does, until it does, the drugs, merely  
2 because they have a similar chemical composition, are not --  
3 that doesn't make them relevant as to all of the same issues  
4 that are the subject of general discovery with respect to  
5 Valsartan.

6 Mr. Stanoch identified really what seems to be the  
7 issue which is not different than the issue for Valsartan.  
8 Chromatographic testing about impurities and with respect to  
9 solvents.

10 Now our view is, that information is going to be  
11 produced as to Valsartan. We've already produced batch  
12 testing for all of our Valsartan produced since 2013. We've  
13 already given them all of the batch testing records that would  
14 -- that's chromatographic testing as to NDMA, and the other  
15 defendants, I'm assuming are going to do the same thing.

16 At some point in time, if there's an issue that comes  
17 up that suggests, you know, we need to look at one of these  
18 other ARBs, with respect to a specific issue, maybe that very  
19 narrow discovery becomes pertinent at that point in time. But  
20 to open the door to four other drugs as to some general  
21 discovery, or even as to the chromatographic testing simply  
22 because they had a similar chemical structure, that is going  
23 to result in disproportion.

24 Now, I can't tell you, I think Mr. Stanoch is right,  
25 I can't tell you how many batch records that is, but we've

1 produced for just Valsartan and for defendants are produced  
2 with respect to ANDAs and DMFs, 200,000 pages.

3 So you're talking about ANDAs, DMFs, for all of these  
4 other drugs. If they want regulatory correspondence for all  
5 of these other drugs, if they want to get into custodial  
6 discovery as to these other drugs, they want to apply search  
7 terms as to these other drugs, they want to find out  
8 organizational charts as to these other drugs, they want sales  
9 as to these other drugs, whatever it is, we are going to,  
10 again, trying to keep the eye on the ball here, which is, you  
11 know, DMF or some residual solvent, impurities with respect to  
12 Valsartan. That's where the Court's going -- the parties are  
13 going to provide that discovery and this kind of an issue, if  
14 it's pertinent at all, should be revealed in specificity later  
15 in the process.

16 THE COURT: Okay. This here is joined -- oh, wait,  
17 we want to hear from some others.

18 MR. SLATER: Free fall.

19 THE COURT: Let's finish up the defendants, then we  
20 will give plaintiffs the last word.

21 MR. REEFER: Judge, I think I would be remiss if I  
22 stood idly by because I think that as has been alluded to  
23 several times over the process, there are defendant-specific  
24 issues. And so, for example, Mylan has recalled only  
25 Valsartan. Mylan has not had any issues with recalls of

1 losartan, irbesartan or any other sartans.

2 The solvent that's being referred to is DMF. Mylan  
3 does not use that solvent in its API manufacturing process.

4 So you see, Judge, I'm not sure what the Court is  
5 envisioning in terms of the issuance of an order, but I think  
6 that it would be outlandish to suggest that Mylan should be  
7 compelled to engage in discovery with respect to products that  
8 no one has alleged are defective.

9 THE COURT: So what's the working theory about what  
10 caused the contamination in Mylan's API?

11 MR. REEFER: Sure. You'll forgive me, Judge, I'm not  
12 a process chemist, but the short story is that Mylan has shown  
13 that this was a result of a recall -- I'm sorry, reuse of  
14 solvent with respect to a very, very specific sort of chemical  
15 pathway that occurs in the two steps of the API manufacturing  
16 process.

17 THE COURT: And when did that start?

18 MR. REEFER: That process was in place since -- I  
19 believe since Mylan entered the market, United States, in  
20 2012.

21 THE COURT: So is Mylan acknowledging that from 2012  
22 until July 2018, it sold contaminated API?

23 MR. REEFER: No, Judge. I don't think that that  
24 blanket statement is necessarily true, because, again, I'm not  
25 a process chemist, but for one, only batches where solvent was

1 reused would be potentially implicated in the nitrosamine --  
2 and again, this is NDEA, it's a separate nitrosamine versus  
3 NDMA, which is sort of the July 2018 origin.

4 And so there are certainly instances, I believe,  
5 Judge, where if fresh solvent, non-reused solvent was used in  
6 a particular lot, you might not see any level of contamination  
7 in that particular lot, and there may be other nuances I can't  
8 explain. But no, Judge, I'm not going to, you know, concede  
9 here that every single batch from 2012 to 2018 was necessarily  
10 contaminated.

11 THE COURT: Thank you, Counsel.

12 All right, Mr. Slater.

13 MR. SLATER: I'm just going to clarify. The only  
14 thing we're interested in with regard to the other sartans is  
15 the manufacturing process and the test results.

16 We're not asking for all the other things that  
17 Mr. Goldberg listed, and, you know, the suggestion that let's  
18 wait and see what happens, Your Honor knows as well as we do  
19 and the defense knows, the depositions of their key witnesses  
20 on why did this happen by necessity, are going to go to, well,  
21 did you manufacture other similar drugs where you didn't have  
22 this issue and why? Or did you have a more significant issue?

23 I mean, the Court has available to it, through the  
24 defendants, samples of actual manufacturing and test results  
25 of multiple drugs, where -- variations in the manufacturing

1 processes, for example, what solvent was used, was it a reuse,  
2 was it new, was it DMF, and we're going -- the more  
3 information we can all have, which is in their file cabinets  
4 that shows us the various manufacturing processes and the  
5 various test results, that information is what we would depose  
6 a witness on and say, well, you have this for three years,  
7 never saw these aberrant peaks. This one, you started to see  
8 aberrant peaks. Did you ever triangulate to try to figure  
9 out, well, why are we seeing this here, why aren't we seeing  
10 this here.

11 And I mean, I could go down the line. Your Honor  
12 knows well what I'm talking about. This is a directly  
13 relevant questioning of these companies in terms of their  
14 knowledge, their notice, the steps they took, the  
15 reasonableness of their reactions, et cetera.

16 So the comparisons as between the manufacturing  
17 processes and the test results of these various drugs, which  
18 are all in the same class and is very similar, is going to be  
19 very important for the parties, for their experts and for the  
20 Court, to ultimately land on why did this happen. Because  
21 Your Honor just, you know, basically laid out, we have  
22 different manufacturing processes, we have different  
23 contaminants, but why would one happen here and not happen  
24 here, and it's helpful that we're having this open discussion  
25 here in court, but clearly, we need this information. Again,

1 all we want is the process and the test results.

2 THE COURT: Okay. Moving on, Issue No. 4, litigation  
3 hold. That's a pretty straightforward issue.

4 Plaintiff, is there anything to add to what you put  
5 in your briefs?

6 MR. SLATER: I think I wanted to just suggest to Your  
7 Honor, having read your decision in *Major Tours* a couple of  
8 times, it may be a process that Your Honor may have already  
9 contemplated, but to suggest a process to handle this in a  
10 practical way.

11 The first thing is that we would ask that Your Honor  
12 order in-camera production of all the hold letters from all  
13 the defendants for all the facilities that are at issue to the  
14 Court to even determine whether or not a privilege is  
15 implicated. Because there may not be information within those  
16 letters that even implicates a privilege and then, Your Honor,  
17 we don't have to talk about privilege.

18 You may look at these letters and say, you know what,  
19 this letter was written by the chief financial officer, it  
20 didn't come from a lawyer, I don't know. I mean, I'm giving a  
21 very simple example, but I think Your Honor has to see the  
22 letters, we can't just talk in a vacuum, No. 1.

23 In the interim, I think that there should be no delay  
24 in them providing the key information that we're going to  
25 need, without production of the letters, they can give that

1 information, and one of the things that we need to know is the  
2 dates, when were the letters issued by each party, to which  
3 facilities, and to which -- by each defendant, No. 1, we have  
4 to know the dates, and I'm reading *Major Tours* because Your  
5 Honor drew the inference in that case, that because of the  
6 delay and because of the scope of who was actually notified of  
7 these obligations, there's an inference of spoliation which  
8 triggered the production.

9 THE COURT: But keep in my mind, in that case, that  
10 the Court was talking in the context of a case where there was  
11 evidence of spoliation.

12 MR. SLATER: Well, my reading of the case and I  
13 understand it when I drilled down on it and I can certainly be  
14 missing something, ultimately, Your Honor drew the inference  
15 that there was spoliation because you said, look, there's no  
16 way that relevant documents weren't destroyed when you waited,  
17 what, three or four years before you instituted this.

18 So there clearly had to be relevant information that  
19 was destroyed or lost.

20 THE COURT: Yes, but the Court -- we knew that, we  
21 knew that in *Major Tours*, we didn't take discovery to find  
22 that out.

23 MR. SLATER: You knew about the delay. So the first  
24 thing we need to know is the dates. There's no -- nothing  
25 privileged about the dates on which litigation holds were

1 issued. It's a legal obligation. We've given you plenty of  
2 law on the other side, and I'm not going to try to argue the  
3 law on whether it's privileged or not, there's obviously cases  
4 that say it's not, and say that giving an instruction is  
5 different than giving advice.

6 Putting that all aside, the date is not privileged,  
7 the distribution list is not privileged, again, very  
8 important. We need to know everybody that got it, because, A,  
9 did they give it to everyone that they needed to and, B, it's  
10 going to help us to identify custodians or confirm custodial  
11 lists, which is very, very important to us.

12 The third thing is, the description of what is  
13 supposed to be held. Very important for us, so we can make  
14 sure the scope of the instructions is adequate, for, again,  
15 reasons that Your Honor discussed in *Major Tours* and  
16 commensurate with that, the way that the terminology is used  
17 and the actual terms that are used will help to inform our  
18 understanding potentially of certain search terms, because we  
19 don't know how they described what should be preserved and  
20 then last, what did they tell people to do.

21 There is nothing about that that's privileged. There  
22 is nothing that is arguably privileged in that. That is basic  
23 information, it's factual information, so they should be able  
24 to provide those components to us now. They should produce  
25 the letters to Your Honor in camera to -- and make whatever

1 argument they're going to make as to why it's privileged.

2 There's nothing for us to say because we won't have  
3 seen them, and then Your Honor I think can make a decision as  
4 to whether or not the letters can be redacted and produced,  
5 whether they could be produced in whole or whether or not we  
6 just need the information that we've asked for today. I think  
7 that's a reasonable approach to this issue.

8 MR. REEFER: Judge, respectfully, I think the  
9 plaintiffs are putting the cart before the horse. I think  
10 Your Honor has already identified, you know, the flaw in the  
11 argument. If you look at *Major Tours*, Your Honor is correct  
12 that before the Court entered the order to produce the  
13 litigation hold, there was already evidence of the spoliation.

14 The spoliation doesn't relate to the failure to  
15 adhere to a litigation hold. The spoliation refers to when  
16 was the duty to retain relevant evidence in place, when was  
17 litigation reasonably foreseeable.

18 And so in this instance, plaintiffs have not come  
19 anywhere close to showing spoliation as that precondition to  
20 the discovery that they're seeking, Judge.

21 The *Bull* case out of the Third Circuit clearly lays  
22 out the four conditions, the evidence that's cited in the  
23 plaintiffs' brief is, I think from 2016 or 2017. There was no  
24 suggestion of any litigation regarding nitrosamines or  
25 Valsartan at that time. There was no recall occurring at that

1 time, and moreover, they haven't shown that any relevant  
2 evidence was discarded before litigation -- I'm sorry, after  
3 litigation became reasonably foreseeable.

4 And with respect to the counterproposal that instead  
5 of producing litigation holds, the defendants just produce all  
6 contents of litigation holds, it would -- the proposal  
7 swallows the rule, Judge. If we're going to give them the  
8 description of the scope of the hold, the recipients of the  
9 hold, when we issued the hold and, Judge, I'll represent on  
10 the record, that at least with respect to Mylan, the  
11 litigation hold was put in place by attorneys, and so --

12 THE COURT: Do you have any objection or do the  
13 defendants object to identifying who received the litigation  
14 holds and the dates?

15 MR. REEFER: Yes, Judge, I believe so.

16 THE COURT: Why is that not relevant and why is that  
17 privileged?

18 MR. REEFER: It's privileged, Your Honor, because  
19 that reflects the mindsets and thought process of the  
20 attorneys who drafted the hold. Respectfully, Judge, we are  
21 engaged in a process right now in the identification of  
22 relevant custodians. The defendants are participating in that  
23 process. We've had an in-person meeting last Friday to  
24 further that process. The information itself, we are  
25 providing. There's no need to pierce what is a privileged

1 document in order to get at the same information.

2 THE COURT: Let me ask you a question. Suppose  
3 plaintiffs are taking the deposition of Ms. Jane Doe who was  
4 the quality assurance manager for your client, and the  
5 plaintiffs ask Ms. Doe, did you receive a litigation hold  
6 letter and when.

7 Do you object to that question on the ground of  
8 privilege?

9 MR. REEFER: I don't believe so, Your Honor.

10 THE COURT: So why, then, can't plaintiff find out  
11 tomorrow who was sent a litigation hold and the date?

12 MR. REEFER: Because, again, Your Honor, it reflects  
13 the process of the in-house counsel, the lawyers in  
14 formulating that list -- it reflects --

15 THE COURT: But my question is, why is it okay to ask  
16 it at a deposition, but not to give plaintiff that information  
17 tomorrow? If it's privileged tomorrow, isn't it privileged at  
18 a deposition? And you acknowledge it's not privileged.

19 MR. REEFER: I'm sorry, Judge, I think I need to  
20 retract my prior statement. I would object, then, if that  
21 question were posed.

22 MR. GOLDBERG: I don't know that that question  
23 wouldn't be objectionable and I'd certainly assert it on  
24 that --

25 THE COURT: On what grounds? Is it privileged?

1 MR. GOLDBERG: I think it does reflect --

2 THE COURT: Why?

3 MR. GOLDBERG: Because that's my client and --

4 THE COURT: That's your client.

5 MR. GOLDBERG: If that litigation hold letter went  
6 from counsel to the witness, that reveals privileged  
7 communication.

8 THE COURT: The fact that the witness received the  
9 litigation hold letter is privileged?

10 MR. GOLDBERG: I would think so, yes.

11 THE COURT: Suppose -- suppose plaintiffs ask the  
12 witness, what did you -- did you do anything to preserve  
13 documents? Is that privileged?

14 MR. GOLDBERG: If the witness -- and I would instruct  
15 the witness, to the extent you can answer without disclosing  
16 privileged information, you can answer the question.

17 And if the witness says, you know, the only thing I  
18 did was listen to my attorney, when I got a -- says to  
19 herself, okay, that's the point. I can say -- I can make that  
20 objection. To the extent you can disclose this information  
21 without disclosing communications with your counsel, you can  
22 answer the question. Witness says, hmm, can't do that,  
23 because the only thing I did was not do anything because my  
24 attorney told me not to do anything, says it to herself.

25 THE COURT: So is there any way for the plaintiffs

1 then to find out if that witness preserved any information?

2 MR. GOLDBERG: Yes.

3 THE COURT: How?

4 MR. GOLDBERG: When there's spoliation, and that's  
5 what the cases said. Let them come to court when they have  
6 evidence of spoliation and then that witness needs to say, how  
7 come on the record, you told us you didn't destroy a document  
8 when you did. That's the whole point here.

9 We cannot let the cart get before the horse.

10 THE COURT: Okay. All right. Thank you. I don't  
11 need to hear anything else, Mr. Slater.

12 MR. SLATER: Please.

13 THE COURT: Okay.

14 MR. SLATER: 30 seconds. There's evidence of  
15 spoliation in this case. We gave it to Your Honor.

16 THE COURT: No, there isn't.

17 MR. SLATER: Where they have shredding bins and  
18 shredding machines and the FDA for both Hetero and Mylan  
19 finding that information was being destroyed.

20 THE COURT: But in fairness, Mr. Slater, I read, you  
21 know, I read the papers, I read the master Complaints, it's  
22 true that -- it's true that there are references in those  
23 papers to shredding and et cetera, et cetera, in 2016, maybe  
24 even in 2017, but the fact of the matter is, I'm not ruling on  
25 this issue, but I think it probably will turn out that the

1 trigger for litigation is when this contamination was  
2 discovered in July '18.

3 So if the duty to preserve did not arise until  
4 July 2018, there can be no spoliation because something may  
5 have been destroyed in 2016 or '17, and I think based on the  
6 record, it's -- it would be very problematic at this time --  
7 I'm not saying it's impossible in the future, but at this time  
8 to argue that the defendants could foresee this litigation in  
9 2016 and 2017.

10 MR. SLATER: We don't know what they foresaw yet. We  
11 will find out. We may find out that there was a litigation  
12 hold issue in 2015 because somebody was actually thinking  
13 about what could happen.

14 THE COURT: Maybe.

15 MR. SLATER: So that's why we need to know. The  
16 other thing is, I wanted to bring to your attention. There  
17 were third parties to this litigation who likely have very  
18 important information and documents. Consultants they brought  
19 in to do testing, analysis, who created some of the  
20 manufacturing processes, et cetera. Did they get the  
21 litigation hold, what did they do, et cetera. So I just  
22 wanted -- I know Your Honor knows that but I just wanted to  
23 make it clear. Thank you.

24 THE COURT: All right. Moving along. Let's go to  
25 the issues where defendants took the lead first, first issue,

1 extent of discovery regarding foreign regulatory materials and  
2 communications. Keep in mind, Counsel, the Court read the  
3 papers. I think it understands the issues.

4 Mr. Goldberg, is there anything you want to add to  
5 what's in the papers?

6 MR. GOLDBERG: This is your issue. This is foreign  
7 regulatory.

8 MR. REEFER: Judge, I think context is important  
9 because we're dealing under Rule 26 with both relevance and  
10 proportionality, and we've discussed at some length some of  
11 the issues with regard to the processes in the facilities, but  
12 what hasn't been mentioned is that Mylan, for example, markets  
13 Valsartan finished dose medications in 46 countries and has  
14 been -- received approval from 14 regulatory bodies.

15 THE COURT: Let me ask you this hypothetical. The  
16 European agency, what is it, EMA or --

17 MR. REEFER: Yes, Your Honor.

18 THE COURT: Okay. EMA did an inspection of Mylan's  
19 plant in February 2018, and -- this is hypothetical -- and  
20 discovered all sorts of problems. They are a foreign  
21 regulatory agency body. Is not that inspection report  
22 relevant to the case?

23 MR. REEFER: Not necessarily, Judge, no.

24 THE COURT: Suppose, again, purely hypothetical,  
25 suppose that inspection report says, be on the lookout for

1 NDEA contamination because of X, Y, Z. Hypothetical, I'm  
2 making that up.

3 Foreign regulatory inspection under defendants'  
4 proposal, that wouldn't be produced, right? Is that not  
5 relevant to the case?

6 MR. REEFER: I think, Judge, like I said, the  
7 argument is twofold. One is relevance and one is  
8 proportionality.

9 THE COURT: Might there be certain categories of  
10 information that are so important and relevant that they have  
11 to be produced even though they're coming from a foreign  
12 regulatory body?

13 MR. REEFER: That category of documents, Your Honor,  
14 would be very, very narrow. But hypothetically, yes.

15 THE COURT: Let me hear from the plaintiffs and I  
16 guess my question to the plaintiffs is this. The Court has  
17 and will order fulsome discovery from the FDA, no question  
18 about it. What material information might exist in foreign  
19 regulatory bodies that you're not going to get from the FDA,  
20 especially since I read in the papers, there's a sharing  
21 agreement amongst the different agencies for anything related  
22 to this recall issue, and is it really likely that any other  
23 defendants, Mylan, Teva, ZHP, whatever, would give information  
24 to the European agency that's relevant to the case that they  
25 wouldn't give the FDA. Because if the FDA has it, you're

1 going to get it. How do you answer that?

2 MR. NIGH: Well, I think very basic, I think it's  
3 important to understand that if it goes to notice, and the  
4 defendants already conceded this, if it goes to notice, that's  
5 -- those are those lines of cases where this information from  
6 foreign regulatory agencies is discoverable.

7 THE COURT: It's relevant.

8 MR. NIGH: It's relevant.

9 THE COURT: It may not necessarily be discoverable.

10 MR. NIGH: It's relevant.

11 THE COURT: It's relevant, but my question is what  
12 are you going to get from a foreign regulatory agency that  
13 you're not going to get from the FDA?

14 MR. NIGH: So when we look at the four different  
15 types of notices -- and I think it's important to understand  
16 that. First, their limited definition is when you actually  
17 discover NDMA contamination. But there are three other types  
18 of notices that we know -- contamination, that you see in  
19 contamination cases that are -- and are here as well.

20 It would be when you start to receive abnormal  
21 testing or customer complaints that are received, such that  
22 when you take a look at those, you could see a trend. They  
23 were -- information that had you investigated further, you  
24 could have become aware of this problem. That's another one.

25 Another -- so that would go to testing and/or DMF of

1 these other drug processes, for example, that we talked about  
2 earlier, where if another country, they're selling this to  
3 another country, the other country has the DMF for one that's  
4 not contaminated, we -- that would be important for us.

5 If we were to see the testing levels for one that's  
6 not contaminated versus one that's contaminated, because we  
7 can compare the two and we can see what's the difference, that  
8 would give us some insight as to how the contamination  
9 occurred.

10 THE COURT: Do you know how many different foreign  
11 regulatory agencies, bodies, what have you, might have  
12 hands-on contact with the manufacturer's facilities?

13 MR. NIGH: Well, there's at least 15.

14 THE COURT: Okay. And you want discovery from all  
15 15?

16 MR. NIGH: Yes.

17 THE COURT: Now, do you -- I guess this is my  
18 question: What are the odds that there is any material  
19 relevant information that is in the hands of those 15  
20 regulatory bodies that is not in the hands of the FDA, given  
21 the worldwide attention, given this problem.

22 MR. NIGH: Well, we see it all the time. I mean,  
23 I've seen it in other litigations all the time, that one  
24 foreign regulatory agency has information that the FDA doesn't  
25 have. And because there is information being shared --

1                   THE COURT: The biggest Class 1 recall in history?

2                   MR. NIGH: Well, this is the biggest Class 1 recall,

3 so I can't say other cases. But I would say that when we come

4 to information here -- and another part is, we talked about

5 sharing. So that's 11 of the foreign regulatory agencies.

6 But there are four that don't share. We've got China, India,

7 Israel. They're not a part of that agreement. So just to

8 assume if they give information to China, that that

9 information made its way to the FDA, I think that's an

10 illogical assumption, that the FDA is going to have all the

11 information that China's regulatory agency has or that India's

12 regulatory agency has.

13                   So the other types of notice that I think are

14 important. When you're notified that you are engaging in

15 risky behavior that can lead to increased chance of

16 contamination, so that would be like a violation of good

17 manufacturing practices.

18                   So whether or not the FDA has every single inspection

19 report, I don't know that they do and that's something that we

20 wouldn't know unless we were to look at some of these other --

21 if we had an order that said all inspection reports from the

22 other regulatory agencies, then we would be able to see if

23 they have the same inspections.

24                   THE COURT: So you want the Court to order all of

25 that to be produced even though the FDA may already have it?

1 MR. NIGH: Yes.

2 The other one would be, you know, another example  
3 with the notice, utilizing a solvent like DMF that is known in  
4 the industry to be risky and often riddled with contamination  
5 problems. This would go to the fourth notice, which is type  
6 2. When you're first developing a drug and you have that risk  
7 assessment that takes place when you first develop the drug,  
8 that's when a lot of times here you look at the chemistry of  
9 it, and we've already seen publications already where chemists  
10 would come out with this issue and said, had they looked at  
11 the chemistry on the front end, they would have been aware  
12 that they should be on heightened alert with the potential of  
13 NDMA formulation.

14 Well, this is important too because this was marketed  
15 overseas before it was marketed here in the U.S.

16 THE COURT: Can you identify for me any specific type  
17 of document and any specific regulatory body that in your view  
18 is important to this case?

19 MR. PAREKH: So the three regulatory bodies that are  
20 very, very important are the regulatory bodies where the  
21 manufacturing facilities were; China, India, Israel,  
22 obviously, because they had much more hands-on inspections and  
23 ability to inspect than the FDA did.

24 MR. NIGH: And we don't have -- the FDA does not have  
25 a sharing agreement with those.

1                   THE COURT: So would you be happy just getting the  
2 inspection reports?

3                   MR. PAREKH: So let me go a little bit more. So  
4 inspection reports for those, obviously, any testing results  
5 that were communicated back and forth from those entities  
6 would be very important to have. And also the processes that  
7 they used to get approval from those bodies to manufacture  
8 these, and what they told those bodies versus what they told  
9 the FDA they were doing is also very important.

10                  Because we've seen in other cases where -- for  
11 example, in Abilify, which we just finished, we saw that what  
12 the defendant was telling the EMA was different than what they  
13 were telling the FDA in the same type of submission.

14                  And so until we know what they were telling these  
15 bodies, we don't know what they have. In addition to those  
16 three, India, China, and Israel, both the EMA and Canada did  
17 independent testing of Valsartan and so those results and what  
18 tests they did may or may not have been communicated to the  
19 FDA.

20                  The other problem with saying, well, they were all  
21 communicated to the FDAs, we don't have access to what the FDA  
22 has. We have FOIA requests. We can get some information from  
23 what the FDA got from other regulatory agencies, but it's not  
24 like we can ask the FDA, hey, please produce to us everything  
25 that you got on Valsartan that you got from other regulatory

1 agencies. They don't -- one, it's a burden that they don't  
2 want to do, and two, they have to spend the time to redact all  
3 of that information. So at the end of the day, we get  
4 redacted documents. If we get them directly from the  
5 defendants, we don't have that issue.

6 THE COURT: Okay.

7 MR. SLATER: Your Honor, one last thing. You asked  
8 the question of what -- is there a likelihood we'll get  
9 different information.

10 THE COURT: Materially different information.

11 MR. SLATER: Yeah. And the answer is a hundred  
12 percent yes, because A, those products were being sold, I  
13 think for the most part, in other countries before the U.S.  
14 So the dates on which the interactions took place, I would  
15 say -- I'll say are close to a hundred percent and the  
16 probability is going to be different. So when was notice and  
17 when were things being discussed specifically germane to the  
18 issues in this case, it's going to be different because the  
19 interactions took place at different times, and that's going  
20 to be critical. As Mr. Parekh just said, what did they tell  
21 those foreign regulatory agencies, and was it the same or  
22 different. In the Abilify case which was just mentioned, the  
23 labels were changed for that drug, which Judge Rodgers handled  
24 that MDL, four or five years or more before they were changed  
25 in the U.S. because different information had been provided to

1 Europe than to the FDA. So the FDA didn't have the  
2 information and Europe said, you have to change these labels  
3 and start warning of these side effects years before they were  
4 warned of in the United States.

5 So there's no expectation that identical information  
6 was being provided and, in fact, there may be communications,  
7 especially perhaps in China where something was mentioned in  
8 some back and forth but there wasn't the incentive to push it  
9 years before they went to market in the U.S.

10 So there's very good reason to produce these  
11 documents. The burden -- you haven't heard anything to  
12 establish a burden. Relevance has already been established  
13 and agreed to. So we need the documents that Your Honor  
14 believes and we've defined what they're most important,  
15 inspection reports, purity, testing. That's what we need to  
16 know. And when I say "purity" --

17 THE COURT: What's purity?

18 MR. SLATER: Bioequivalence. Purity has to do with  
19 whether there's contamination or not. Because again, there  
20 may be findings on tests that are not labeled as this is what  
21 this is, but they're aberrant and they require investigation.

22 THE COURT: Okay. No. 2 is done.

23 No. 3, the extent of discovery regarding each  
24 applicable defendants' finished dose manufacturing process.  
25 Anything you want to add to the papers?

1 MR. RUBENSTEIN: No, just that, you know, we're not  
2 trying to say that any --

3 THE COURT: I'm sorry, I skipped an issue. I  
4 apologize. We'll get there.

5 MR. RUBENSTEIN: Okay.

6 THE COURT: 2, the extent of discovery regarding  
7 foreign sales, marketing, and agreements.

8 Defendants, anything you want to add to what's in the  
9 papers?

10 MR. REEFER: Judge, I think the briefs are laid out  
11 there pretty well.

12 The only thing I would mention, Judge, is that the  
13 stated justification that plaintiffs provide for, you know,  
14 what could be construed as a very broad category of discovery,  
15 which is foreign sales and marketing, that the retort is,  
16 well, how would we know if a customer, presumably a finished  
17 dose customer like Novartis, would have alerted the API  
18 manufacturer of an issue if we're not entitled to this very  
19 wide swath of information. And the response I would have to  
20 that is, if that's what the plaintiffs are looking for, if  
21 they would like the defendants to produce core communications  
22 from customers relating to what's referred to in the papers as  
23 aberrant spikes in chromatographs, that's something that we  
24 would be willing to reproduce, but the problem is, you know,  
25 going beyond that, there's no justification for it, there

1 hasn't been any stated justification for it, and so with that  
2 proviso, Judge, I think the papers lay it out there.

3 THE COURT: Thank you. Anything you wanted to add to  
4 that?

5 MR. PAREKH: Just a couple of things. One is -- I  
6 mean, we're not asking for every single piece of sales  
7 information and every single piece of marketing data. That's  
8 not what the RFPs ask for. And so, you know, the things that  
9 we're looking for are what we laid out in the brief, which is  
10 communications between either end users or, you know,  
11 somewhere along the supply chain, talking about things like  
12 out-of-spec situations where they've returned product. We  
13 know that that happened. We don't know who that happened  
14 with, because that information is redacted, and if they  
15 happened to be foreign customers, according to defendants'  
16 position, we don't get any of that. I mean, their position in  
17 their brief. They stated a different position at this point,  
18 saying that they will provide some of that. But we need to be  
19 able to pin that down.

20 The other aspect of it is we also need to know what  
21 the process differences are between some of these customers.  
22 For example, the process that was used for sale to customers  
23 in Japan, specifically, required one extra step in the solvent  
24 quenching process -- I think it's the quenching process --  
25 that apparently resulted in an end product with no NDMA

1 impurity. Why was that used solely for the Japanese  
2 customer? What did the Japanese customer know that other  
3 people didn't?

4 THE COURT: So why are you just bringing this issue  
5 to the Court's attention now, and why wasn't this issue in the  
6 extensive letter briefs the Court received?

7 MR. PAREKH: It was in the letter briefs.

8 THE COURT: It was?

9 MR. PAREKH: Yes.

10 THE COURT: Specifically referring to Japan?

11 MR. PAREKH: It didn't refer to Japan. We had to do  
12 some digging to figure out that it was Japan, but I think that  
13 happened last night, and I apologize, but we did put in that a  
14 customer had this, we just didn't know that it was Japan at  
15 that point, or we missed it, and I apologize. But, you know,  
16 we know that that happened. We don't know as to other  
17 customers, whether or not they had their own specs. We  
18 believe one of the other customers, Par, actually was buying  
19 ZHP's product using Process 1 when ZHP discontinued Process 1,  
20 Par decided that we're not going to buy API from ZHP anymore.  
21 It would be really good to know why they decided that. What  
22 about their Process 2 did Par not like? What did they know?  
23 What did they communicate to ZHP about it?

24 I mean, these are just things that we gleaned from  
25 bits and pieces in the core discovery. We don't know what we

1 don't know a lot of the time. This is us trying to piece  
2 together that puzzle. That's why we need this information.

3 THE COURT: Issue 4, the extents of discovery  
4 regarding Valsartan testing.

5 Oh, I'm sorry, here we go again, I skipped one.

6 3, the extent of discovery regarding each applicable  
7 defendants' finished dose manufacturing process. Back to  
8 Teva.

9 MR. RUBENSTEIN: Right. So, you know, we're not  
10 saying that documents are wholesale barred from the finished  
11 dose manufacturers. You know, things like the API testing,  
12 the certificates of analysis, quality complaints, they would  
13 clearly be discoverable, but in terms of the actual, you know,  
14 nuts and bolts converting, formulating the API from the API  
15 into the finished dose pill, you know, they've asked for  
16 documents identifying, you know, patented machinery that was  
17 used and, you know, all the external excipients and inactive  
18 ingredients, things like that that were used. You know,  
19 that's clearly irrelevant, overly burdensome, you know, not  
20 going to lead anywhere.

21 You know, we keep talking about inspection reports  
22 and things like that. So, you know, these manufacturing  
23 facilities for the finished dose, they make dozens if not  
24 hundreds of products. So if there's an inspection report or  
25 an observation about a product that's completely unrelated to

1 Valsartan, we don't see why that that's relevant because, you  
2 know, it's not connected to Valsartan or, you know, detection  
3 of impurities or anything like that. So we don't see how  
4 something like that would be relevant if it's, you know, about  
5 a completely different drug, because like I said, these  
6 facilities make dozens if not hundreds of different products.

7 So, you know, we're just trying to reign in the scope  
8 here. You know, clearly, there's going to be some things that  
9 are discoverable but clearly there's -- requests they are  
10 beyond the pale.

11 THE COURT: You're not taking the position that all  
12 discovery regarding the finished dose manufacturers is off  
13 limits --

14 MR. RUBENSTEIN: No.

15 THE COURT: -- it just has to be focused and relevant  
16 to the case.

17 MR. RUBENSTEIN: Correct.

18 THE COURT: All right.

19 Plaintiff?

20 MS. HILTON: Your Honor, if I may, I'm glad to hear  
21 that the finished dose manufacturers are committing to some  
22 production, but, you know, first of all, I think, you know, I  
23 need to make the point that API manufacturers in this case are  
24 also finished dose manufacturers and so they have taken the  
25 position that they are some separate and silent entity and,

1 therefore, not required to do the same amount of discovery in  
2 into their finished dose practices as a Teva or a Torrent or  
3 an Aurolife. So that's our first issue here. We want to make  
4 sure that both the API manufacturers are going to commit to  
5 the same level of discovery of their finished dose facilities,  
6 as the finished dose manufacturers, because API manufacturers  
7 are finished dose manufacturers.

8 So, that's sort of like a -- we have a schism up  
9 there, and so that's something that, you know, we sort of seek  
10 the Court's --

11 THE COURT: Correct me if I'm wrong, but I was  
12 assuming that although it may be one facility, the API  
13 manufacturing and the finished dose manufacturing are  
14 segregated.

15 MS. HILTON: They are, Your Honor.

16 THE COURT: So, it's not like if the FDA comes and  
17 does an inspection, they necessarily will do both at the same  
18 time. They might do one and not the other. That was my  
19 assumption, I don't know, but it's not like it's one -- maybe  
20 I'm wrong. I didn't assume it's one big room where everything  
21 is done finished dose and API manufacturing.

22 MS. HILTON: You're correct, Your Honor, but the --  
23 you know, I'll state this, finished dose manufacturers in core  
24 discovery produced establishment inspection reports for their  
25 finished dose manufacturing facilities.

1                   API manufacturers are of the position that they are  
2 not required to produce this discovery at all.

3                   And so this is the schism we have. So we're trying  
4 to seek a commitment that first of all before we decide what  
5 finished dose manufacturers are going to produce, that API  
6 manufacturers are going to fall in line with what the other  
7 finished dose manufacturers are producing when we decide what  
8 that scope is.

9                   THE COURT: You want it to be coextensive? In other  
10 words, whatever the API produces, the finished dose produces?

11                   MS. HILTON: No, I want it to be whatever the  
12 finished dose produces, the API produces. Because the way  
13 that -- you know, my understanding of it is, and like everyone  
14 in this room, I'm not a process chemist, but, you know, the  
15 API is made in one facility. It is then shipped to another  
16 facility where it is tested, you know, you go -- stability  
17 testing, the chromatography, it is then manufactured in a pill  
18 and then distributed, right? API manufacturers, as I  
19 understand it, and they can surely correct me if I'm wrong,  
20 are saying that they are only going to produce documents  
21 related to the API and not what happens once the API leaves  
22 and arrives at their finished dose facilities, whereas the  
23 finished dose manufacturers, Teva, Torrent, Aurolife, have  
24 committed to producing documents at these finished dose  
25 facilities, and so that's the schism that we find ourselves

1 in.

2 THE COURT: Okay.

3 MS. HILTON: And that's just -- that's just the  
4 larger issue, but we also have issues of what the finished  
5 dose manufacturers would produce, which is to say, you know --

6 THE COURT: What do you want?

7 MS. HILTON: Well, first of all, with respect to --  
8 you know, I was a participant in the request for production,  
9 the meet and confers on manufacturing. You know, surely at  
10 this point in time, like you've said, can't commit to what we  
11 don't know, what we don't know happens at the finished dose  
12 process, but there are key documents that we can receive.

13 THE COURT: Such as?

14 MS. HILTON: Such as establishment inspection reports  
15 that list all of the exhibits that are provided by the  
16 finished dose manufacturer.

17 THE COURT: What else?

18 MS. HILTON: Quality assurance documents, standard  
19 operating --

20 THE COURT: Wait a minute. See, quality assurance  
21 documents, you want to know if it's the right color or the  
22 right size or the right weight?

23 MS. HILTON: I think when I say "quality assurance  
24 documents," you know, we want to know specifically, and I'm  
25 not limiting it to this, but we want to know what they are

1 going to do when they receive the API, what is the testing  
2 protocol for that, what is the model testing protocol, what  
3 are they supposed to do when they notice an aberrant peak with  
4 respect to the API. Are those testing protocols validated.  
5 All of these things go to, you know, back to the issue of  
6 Novartis. How did Novartis identify a problem when all of the  
7 defendants did not?

8 And so that's sort of -- that discovery will help  
9 inform upon whether there is some aspect of the finished dose  
10 manufacturing that may be implicated. But we need to see  
11 those deviation reports, we need to see, you know, those  
12 out-of-spec testings and out-of-trend testings before we can  
13 make a determination as to, you know, whether we don't need X,  
14 Y or Z, and that's what we told the defendants in our meet and  
15 confer, with respect to the API manufacturing, too. We have  
16 to understand where the problems are being presented before we  
17 can start limiting.

18 THE COURT: Okay. Next. Extent of discovery  
19 regarding Valsartan testing. There is no issue regarding the  
20 -- pronouncing it right, chroma --

21 MR. GOLDBERG: Chromatography, Your Honor.

22 THE COURT: Chromatography. Is there an issue with  
23 bioequivalence?

24 MR. GOLDBERG: I don't think there is. I just think  
25 when it gets to chromatography, chromatography could be used

1 in different ways and what we're talking about, where we think  
2 the focus should be is with respect to impurities, like  
3 nitrosamines and potentially residual solvents, because we're  
4 using a solvent, Mylan is using a different solvent, but that  
5 should be where the chromatography testing focuses and then  
6 the bioequivalence to the extent it hasn't already been  
7 produced, and mind you, most of it's been produced because  
8 that is in the DMFs and what we communicate with the FDA on.  
9 But that's where we think it should be.

10 THE COURT: Plaintiffs, is that a good place to  
11 start?

12 MR. WILLIAMSON: Well, that's a good starting point,  
13 Your Honor, but I believe that, again, we don't know what we  
14 don't know. What we would like for the defendants to do is to  
15 produce a list of all of the testing that is performed at  
16 their facilities. We can then take the list to our experts  
17 and have our experts review and tell us whether they believe  
18 in addition to what they've already agreed to give us if  
19 anything else is relevant and we can meet and confer with the  
20 defendants and if we both agree, then there'll be productions.  
21 If not, we can come back to Your Honor on December 11th or  
22 whenever you advise us to do that and we will say, Your Honor,  
23 we need X, Y and Z because of this.

24 THE COURT: Got it.

25 MR. GOLDBERG: Your Honor, just one point on that

1 list. We produced, and I'm sure it's with the other  
2 manufacturers, a list of the kinds of things we test for.  
3 It's not a mystery. This is Page 9782 of Prinston's  
4 production. They have experts. Their experts should know if  
5 testing about appearance or solubility or identification are  
6 things that would bear on testing about impurities. So that  
7 list is there.

8 THE COURT: All right. With regard to this list, and  
9 we're getting to the end, 7 and 8, I, Court, understands have  
10 been -- are agreed upon. So the last issue, and I'm glad  
11 we're saving it for last and then we'll take a break, is the  
12 relevant time period for the custodial search, and I've  
13 already confessed that this is the issue the Court needs help  
14 with.

15 I think a good place to start is let's, for each  
16 defendant that we're talking about, find out what the proposal  
17 is from each side.

18 So Mr. Goldberg, ZHP, what are you proposing?

19 MR. GOLDBERG: Your Honor, ZHP proposes that --

20 THE COURT: Just give me the date.

21 MR. GOLDBERG: Sure.

22 THE COURT: And then we'll come back to argument.

23 MR. GOLDBERG: I would say January 1st, 2015 for  
24 general custodial discovery with respect to the document  
25 request and how the Court rules as to those things. With

1 respect to manufacturing specific questions, questions about  
2 chromatographic testing, about impurities, bioequivalency, to  
3 the extent we can be specific and go back in a manufacturing  
4 process, we acknowledge that we have made a change in  
5 December 2013, we acknowledge that change started in 2011, and  
6 if there are specific questions about the process even before  
7 2011 -- granted, it should be very specific as to the  
8 pertinent issues, we think we can go back there. But for  
9 general discovery, January 1, 2015, because any of our API  
10 only could have been sold in the U.S. after that point in  
11 time.

12 THE COURT: Plaintiff, we'll start with the date,  
13 we're going to circle back to the argument. What date are you  
14 proposing?

15 MR. HONIK: Your Honor, the date we propose coincides  
16 with the first Drug Master File application, would be  
17 September of 2007, and in point of fact, certain of the  
18 questions we've propounded or requests for documents predate  
19 that.

20 And the reason that we've done that, if you want to  
21 hear a little argument on that.

22 THE COURT: Can we come back to argument?

23 MR. HONIK: Yes, we can.

24 THE COURT: I just want to get this list.

25 Mylan, what are you proposing?

1 MR. REEFER: Judge, we propose September 21, 2012,  
2 the date that the first finished dose product was approved by  
3 FDA for market in the United States, with the proviso that in  
4 core discovery we all be produced three ANDA files and the  
5 DMF, which sheds light on the process development issues.

6 THE COURT: What are you proposing for Mylan,  
7 plaintiffs?

8 MR. HONIK: Your Honor, let me just point out  
9 something generally for each of these. The answer in every  
10 instance is whenever their research and development began  
11 related to their manufacturing process. In the case of API,  
12 when they did the research that led to their submission of  
13 their Drug Master File.

14 In Mylan's case, they did that in August of 2006, and  
15 that's not a hard cutoff and we need to articulate that the  
16 starting date in our mind is when the run-up to that occurred,  
17 when they were doing research and development activities --  
18 and this is true for all the defendants, whether finished dose  
19 or API, where they were deliberating on the choice of a  
20 solvent, the choice of catalyst, the risk benefit profiles,  
21 inspecting, for example, the patent that Novartis had as the  
22 innovator. All of that consideration that the defendants had  
23 is directly germane to the issue in this case and nothing  
24 exemplifies it, frankly, more than the ZHP example that  
25 Mr. Nigh spoke to earlier.

1 I have may engendered some confusion by using the  
2 term "DMF" because there's DMF solvent and there's the Drug  
3 Master File. And what I had meant to convey -- and this is  
4 very important to illustrate our thinking about the timeline  
5 here.

6 In 2007, when they first received approval for  
7 Process 1, which did not use DMF, they had no problems with  
8 contamination. Lo and behold, with the beginning of Process 2  
9 in 2010 and then the second iteration of that, in both  
10 instances, they did have a problem.

11 Our experts need to understand why they didn't have a  
12 problem with Process 1, which in ZHP's case goes back to 2007  
13 and understand what their research and development told them  
14 in the run-up to that, about that process, which was  
15 apparently a good process, it didn't produce impurities.

16 So, what I'm getting at is I can tell you, when they  
17 either put in their ANDAs or put in their DMFs with FDA, but  
18 we think with respect to those processes, we need to have the  
19 research and development that led up to that. So I can give  
20 you the date, but in point of fact, we want the period that  
21 led up to that as well.

22 THE COURT: So I wrote down August 2006, but you may  
23 want earlier than that.

24 MR. HONIK: Yes. And our request for production is  
25 specific. So in the handful that we focus on around the ANDA

1 filing, we are specific and use words not dates to suggest  
2 that we want your research that led up to certain components  
3 of their ANDA filing, because that's their representation to  
4 the regulatory body saying, this is how we want to make this  
5 pill, this is the possess we want to employ, these are the  
6 quality controls that we want to use and we -- and our experts  
7 need to understand what that was, what their thinking was,  
8 what the basis for that approval was.

9 THE COURT: I got it.

10 MR. HONIK: So long-winded way of saying, yes, the  
11 ANDA filing for Mylan was August of 2006.

12 THE COURT: Teva, what's your proposed date?

13 MR. RUBENSTEIN: So, the first time that Teva ever  
14 sold a Valsartan drug in the United States was March of 2013,  
15 and we propose to go back to January 1st of 2013 for the  
16 run-up to the launch for whatever testing of API for the  
17 product that was going to ultimately be sold would have been  
18 happening.

19 THE COURT: And plaintiff?

20 MR. HONIK: Teva was a second filer. In January of  
21 2005 they did a ton of research and development with respect  
22 to that Abbreviated New Drug Application.

23 THE COURT: Got it.

24 MR HONIK: But we'd like to see the run-up to that as  
25 well.

1 THE COURT: Torrent?

2 MS. NAGLE: Torrent proposes January 21st, 2014,  
3 which is a few months prior to the first time that Torrent  
4 sold Valsartan in the U.S.

5 THE COURT: And plaintiff as for Torrent.

6 MR. HONIK: Their ANDA filing was in June of 2009 and  
7 we'd like the run-up data and research on that as well.

8 THE COURT: Okay. Is there a party Aurolife.

9 MS. HEINZ: Yes, Your Honor.

10 THE COURT: Sorry, I forgot all about you today.

11 MS. HEINZ: No problem. Jessica Heinz.

12 We took the position that the relevant time period is  
13 March 21st, 2013. That's when our first ANDA was approved by  
14 the FDA for a Valsartan product.

15 THE COURT: And plaintiffs' date for Aurolife?

16 MR. HONIK: Your Honor, we have yet to receive any  
17 discovery regarding Aurobindo Limited and thus we don't know  
18 the date on which the Indian entity filed its DMF for  
19 Valsartan API. So we don't know with any degree of certainty,  
20 but at a minimum we should begin at sometime prior to June of  
21 2010, certainly. And that's the date by which the U.S. entity  
22 submitted their ANDA submission to the FDA. But it could be  
23 earlier.

24 THE COURT: Okay. Let's circle back.

25 Is ZHP now -- you're proposing general custodian

1 January 1, 2015 testing, may go back to 2013 or 2011. The  
2 2015 date, that is what?

3 MR. GOLDBERG: That's triggered by the ANDAs that  
4 were -- the ANDA that was approved for our finished dose and  
5 that the API that we supplied was approved with the ANDAs.  
6 Like Torrent's ANDA happened in 2015.

7 So any of our API could only have been sold in the  
8 U.S. after January 1, 2015.

9 THE COURT: But before that, ZHP was selling API  
10 around the world?

11 MR. GOLDBERG: Not in the U.S.

12 THE COURT: When did it start selling API around the  
13 world?

14 MR. GOLDBERG: That, I don't have the answer to now.  
15 I can certainly get that to you.

16 THE COURT: Do you know, plaintiffs? But plaintiffs  
17 are saying that it was --

18 MR. HONIK: We don't know the precise date. I  
19 presume it predates 2007.

20 THE COURT: That's what I was going to say. At least  
21 as to --

22 MR. HONIK: At least as far back at 2007.

23 THE COURT: Okay. And the plaintiffs propose  
24 September 2007 because that was the date of the first DMF --

25 MR. HONIK: Correct, to the FDA.

1                   THE COURT: Okay. And Mylan is proposing  
2 September 21, 2012, because that's the date of FDA approval  
3 for sale in the U.S.?

4                   MR. REEFER: Correct, Your Honor.

5                   THE COURT: Were they selling finished dose Valsartan  
6 somewhere else before that date?

7                   MR. REEFER: I don't know, Judge, frankly.

8                   THE COURT: But you want, plaintiff, August '06?

9                   MR. HONIK: Yes, sir.

10                  THE COURT: Because -- at least August '06 because  
11 the problem --

12                  MR. HONIK: That's when the ANDA filing occurred.

13                  THE COURT: Teva, January 1st, 2013, that's a little  
14 before the start of actual U.S. sales?

15                  MR. RUBENSTEIN: Correct.

16                  THE COURT: And when was ANDA approval?

17                  MR. RUBENSTEIN: In May of -- I'm not exactly sure.

18                  MR. HONIK: The ANDA was substantially completed  
19 January 7th, 2005.

20                  MR. RUBENSTEIN: But that's not when it was approved.

21                  MR. HONIK: That's when it was substantially  
22 completed, where the approval is largely irrelevant, but the  
23 work that Teva did in supplying the information to the FDA was  
24 complete by 2005.

25                  THE COURT: So let's use Teva as an example. The

1 parties are disputing whether discovery should be produced  
2 between January '05 and January 2013. That's a long time.  
3 That's eight years. What are you looking for during that  
4 eight years that wouldn't be produced if we used the start  
5 date as January '13?

6 MR. HONIK: We would be losing all of the information  
7 that Teva researched and developed in evaluating the process  
8 for making the pill that they put into this marketplace.

9 We know, because of the process of building into an  
10 ANDA, that the company invariably had to do extensive  
11 evaluation of processes and evaluation of, for example, the  
12 innovator patent. All of that is spadework that all of these  
13 companies do in the run-up to it.

14 And so if it's true what Mr. Goldberg has suggested  
15 all along, that this is about the manufacturing process, the  
16 choices that were made surrounding that, the solutions that  
17 were employed, the solvents that were employed, we need to  
18 understand the thinking that went into the company's choices  
19 and the thing that would most reveal that to us, as far as we  
20 can see, would be the support for their Abbreviated New Drug  
21 Applications.

22 THE COURT: So suppose, hypothetically, when we  
23 identify the custodians for Teva, I don't know how many, let's  
24 just pick a number, 10, out of X number, people who worked in  
25 the laboratory and the quality control department, you're

1 saying to Teva, because we want to know how you developed this  
2 manufacturing process back to January '05, these people who  
3 had nothing to do with that, we're going to search eight years  
4 worth of their records. Right? Because you want January '05,  
5 Teva wants January '13 and that's eight years. You're  
6 interested in the manufacturing process. Suppose these  
7 quality assurance people and laboratory people who had nothing  
8 to do with the manufacturing process, you're saying to Teva,  
9 they have to search those eight years of records?

10 MR. HONIK: Well, if I understand the hypothetical,  
11 Judge, it will be self-limiting because we're going to agree  
12 separately to search terms, and if under your hypothetical  
13 they've had nothing to do with it, then nothing will come up.

14 THE COURT: No, nothing will come up, but they still  
15 have to search.

16 MR. HONIK: But your hypothetical says -- we're  
17 talking about these 10 custodians, right? And we're going to  
18 agree at some point, or the Court will direct appropriate  
19 search terms and the question is how far back do you have to  
20 go in the database.

21 THE COURT: Exactly.

22 MR. HONIK: And, yes, I would -- I want them to go  
23 back to the point in the company's history when it was  
24 weighing and considering all the options about how they were  
25 going to manufacture this bill and it will be self-limiting if

1 indeed one of the ten, in your hypothetical, if he or she  
2 doesn't have anything in their cache of data, then nothing  
3 will come up.

4           But the question it seems to me is, should we have  
5 the right to ask to go back. Is there some factual basis that  
6 supports the idea that going back to this more distant point  
7 in time -- I understand it's eight more years, it's not an  
8 insignificant period of time. Is there a basis to suggest  
9 that there may be something there that is germane, if not in  
10 this custodian, then in that custodian. And because we know  
11 in the run-up to an ANDA filing, not when they launched, but  
12 in the development prior to the launch, that is -- we know it  
13 from many cases reveals a great deal of their internal  
14 thinking and weighing, should they use Process 1. What's the  
15 reason that Par said, we don't want the DMF solvent process,  
16 we want the other process.

17           We know that much in this very case. Are there other  
18 customers, are there other experiences that these finished  
19 dose manufacturers have that inform the way they elected to  
20 support their ANDA.

21           It's relevant to go back and if there are no  
22 documents, or it's -- you know, it will be self-limiting.

23           MR. SLATER: Can I just add one thing to that?  
24 Specific example. During the process of developing these  
25 manufacturing processes, they had to consider, for example,

1 solvents. They had to evaluate which ones we're going to use.  
2 Are we going to use reused solvents? Are we going to use new  
3 solvents? What are the risks? What is the quality assurance  
4 evaluation? Because, for example, we know a lot more about  
5 CHP at this point, because we had that meeting. What was  
6 quality assurance's role in this? What did they find? What  
7 did they say; what were their concerns?

8 I mean, the whole run-up is their body of knowledge  
9 that leads up to where we get to. It's not like at a fixed  
10 point in time everything starts. It's not like a baby is  
11 being born. This is a process where it was being constructed  
12 for years and years and their process is going to be relevant,  
13 and it's clearly relevant, it's clearly very significant  
14 because when we depose these witnesses, obviously we're going  
15 to say, well, what went into this decision, and are we going  
16 to get objections, you can only go back to 2013, January 1st,  
17 even though the decision was made based on information they've  
18 developed for six or seven or eight years before that. That  
19 would be inequitable and I think it would cut us off from  
20 very, very directly relevant evidence.

21 MR. HONIK: So to use a metaphor that Ms. Goldenberg  
22 used last night, she said, the baby's baked by 2013, the  
23 baby's baked. And so we need to go back in this case, in  
24 Teva's example, to 2005, when the baby was starting to be  
25 created.

1                   MR. RUBENSTEIN: Your Honor, if the ANDA file was  
2 submitted in 2005, to the extent there were any changes  
3 between 2005 and March to that ANDA file, that would be in the  
4 FDA correspondence with respect to that ANDA file, which the  
5 plaintiffs have.

6                   So, you know, I don't know what they're talking about  
7 all these different solvents that need to be considered.  
8 That's not in the finished dose product. And, you know, quite  
9 frankly, all that really matters is what did they come to  
10 market with. Not always considered seven years before they  
11 came to market. What did they sell on the market?

12                  MR. HONIK: Here's a perfect Teva example, and I was  
13 reminded of this. Teva at one point in time bought a  
14 pharmaceutical entity called Cobalt, C-O-B-A-L-T, who bought  
15 ZHP API. They specifically requested Process 1 when Process 2  
16 was in place. They refused to take Process 2 for reasons we  
17 suspect having to do with impurities associated with that  
18 process.

19                  That's a Teva entity. If the Court cuts this off at  
20 2013 or something close in time that's arbitrary, we will miss  
21 that sort of judgment making on the part of Teva, a defendant  
22 in this case.

23                  There's a reason their predecessor company which they  
24 acquired requested Process 1, and if we have an arbitrary  
25 cutoff that postdates that decisionmaking, it will never be

1 revealed to us. And if it's true, as Mr. Goldberg has said  
2 time and again, it's about the manufacturing process, the  
3 decisions and choices that these companies made around it, we  
4 need to pull back the curtain and understand their thinking  
5 about it.

6 MR. RUBENSTEIN: And, Your Honor, that -- I mean,  
7 that might be a specific example, but I don't even know that  
8 that relates to the ANDA that was filed in 2005. That could  
9 have been a different ANDA, which I believe it was.

10 So, I mean, you know, coming up with these  
11 hypothetical situations doesn't justify Teva having to go back  
12 an additional eight years, find all the different custodians  
13 that there could have been during that eight-year time period,  
14 you know, just to pull a rabbit out of a hat, basically.

15 THE COURT: Got it.

16 Torrent, January 1st, 2014, can you refresh my  
17 recollection about why you picked that date?

18 MS. NAGLE: Sure, Your Honor. That date is a few  
19 months prior to the first sales of Valsartan in the U.S.

20 THE COURT: And I have defendant -- I'm sorry,  
21 plaintiff at least as early as June 2009.

22 MR. HONIK: That's correct.

23 THE COURT: And last but not least, Aurolife, could  
24 you refresh my recollection about May 21st, 2013.

25 MS. HEINZ: Yeah, it was March 21st, 2013.

1 THE COURT: I'm sorry, March 21st.

2 MS. HEINZ: That was when the FDA approved our first  
3 Valsartan product for sale in the U.S.

4 THE COURT: When was FDA approval of Torrent? You  
5 gave me the sale date. What was the FDA approval date?

6 MS. NAGLE: I'm not quite sure.

7 THE COURT: It had to have been earlier than that,  
8 right?

9 MS. NAGLE: Yes.

10 THE COURT: All right.

11 MR. HONIK: Your Honor, it was pointed out to me that  
12 we missed or haven't thus far discussed Hetero or Camber from  
13 whom we have --

14 THE COURT: Oh, are they finished dose people, too?

15 I know Hetero and Camber -- well, I thought Hetero  
16 wasn't served yet.

17 MS. HILTON: That's the U.S. entity, Hetero USA,  
18 which is served, which is represented and acted as the  
19 regulatory U.S. agent for Hetero Drugs, Hetero Labs.

20 THE COURT: That reminds me of an issue. The FDA  
21 liaison issue, is that what they are?

22 MS. HILTON: Yeah, they are the registry agent,  
23 they're the liaison.

24 THE COURT: And they're taking the position that  
25 they're not an API manufacturer or finished dose manufacturer.

1 MS. HILTON: Correct, and there Camber is a similarly  
2 situated entity. It is taking the position that it is neither  
3 a manufacturer, but it is the distributor of the product, the  
4 seller of the product in the United States.

5 THE COURT: Distributors are a different category, we  
6 agree. I think we're going to finalize that in January,  
7 but --

8 MS. HILTON: Correct. But distributors, as to, like  
9 a McKesson or a Cardinal, is, to us, to plaintiffs, is a  
10 different type of distributor than a vertically integrated  
11 U.S. arm that sells drugs to McKesson and Cardinal.

12 THE COURT: Let's put them in the same category.

13 How many different FDA liaisons do we have in the  
14 case besides Hetero?

15 MS. HILTON: Huahai U.S. is in this case.

16 THE COURT: I'm sorry?

17 MS. HILTON: Huahai U.S.

18 THE COURT: Well, we're dealing with that.

19 MS. HILTON: I think Hetero USA is the only one --

20 THE COURT: So what do you want from them that you  
21 don't have?

22 MS. HILTON: Well, you know, first of all, I think we  
23 have basic agreement, but we believe that we should be  
24 selecting custodians for these entities and we believe.

25 THE COURT: Have you started yet?

1 MS. HILTON: We've sort of started the process.

2 THE COURT: Can we put that until January? Because  
3 that would open up a whole new door. I should -- if I had to  
4 do it again, I would put that on the macro issue, what to do  
5 with the FDA liaisons, but we didn't. Can we save that for  
6 January? I think we have our hands full with the API and  
7 finished dose people. Okay?

8 MS. HILTON: Yes, Your Honor.

9 THE COURT: All right. Before we break for lunch --  
10 when we come back from lunch, 2 o'clock, you'll get the  
11 Court's oral opinion on all these issues, then we will meet  
12 with Judge Kugler. Any other issues you want to address now?

13 MS. GOLDENBERG: Yes, Your Honor, issue No. 5 from  
14 the defendants' brief that we didn't cover, relating to other  
15 adverse health effects.

16 THE COURT: Oh, did I skip an issue? I'm sorry.

17 MS. GOLDENBERG: We did. I think we can keep it  
18 pretty quick.

19 THE COURT: Okay.

20 MS. GOLDENBERG: Here's what we want, so we'll start  
21 with that.

22 THE COURT: How refreshing.

23 MS. GOLDENBERG: We want information, of course,  
24 pertaining to cancer and I think we're on the same page about  
25 that.

1                   THE COURT: Are we talking about about from day one  
2 or after the contamination was discovered?

3                   MS. GOLDENBERG: No, from day one, Your Honor.

4                   THE COURT: See, here's the problem. How do we deal  
5 with this? They're a drug company. Clearly, they had to do  
6 health tests on whether this drug causes heart problems,  
7 probably cancer. You want -- I mean, that's not relevant to  
8 the case, is it? You want to know health effects related to  
9 the contamination.

10                  MS. GOLDENBERG: Well, here's why it's important  
11 because I think we all remember from our previous case  
12 management conference where we saw a very long list of  
13 conditions that the defendants gave is that they're going to  
14 use to defend as specific causation. So this issue, really on  
15 the personal injury side, it relates to specific causation,  
16 and on the class action side, it relates to bioequivalence and  
17 the benefit of the bargain. So on the specifics causation  
18 side, if the defendants are saying, look, the only injuries in  
19 this case are cancer, we're on the same page, then we need  
20 that information.

21                  But beyond that, they're going to say to our clients,  
22 were you ever exposed to wood or kryptonite, as we joked last  
23 time. But to the extent they have any information about  
24 anything that they've put on the plaintiff fact sheet causing  
25 cancer, we should be entitled to that information.

1                   THE COURT: So you want to know, like, when they were  
2 developing Valsartan, whether they investigated whether it  
3 causes cancer?

4                   MS. GOLDENBERG: Not whether Valsartan causes --  
5 well, I mean I would think that they would, but if there's  
6 information that they have about the drug or any of the  
7 contaminants causing cancer, precancerous condition or injury  
8 to any of the organs that we have talked about, digestive  
9 tract, then that's going to be important.

10                  The other --

11                  THE COURT: Okay. So right now, we're just dealing  
12 with health effects of exposure to NDEA NMBA, whatever it is,  
13 right? You want to know that, basic?

14                  MS. GOLDENBERG: Right, that's one thing we want to  
15 know.

16                  THE COURT: Okay.

17                  MS. GOLDENBERG: On the class side, what we've seen  
18 on Page 4 of the defendants' brief is a heading that says  
19 Valsartan was the active pharmaceutical ingredient contained  
20 in a safe, effective and life-saving heart medication.

21                  So now we have a defense that we have to rebut that  
22 says Valsartan is going to save lives, right? That's what  
23 they're going to get up and say to the jury, that this drug  
24 saved our clients' lives and if they hadn't taken it, they  
25 would have suffered some other type of health problem.

1                   So on the class action side, there are going to be  
2 arguments about efficacy and whether or not the drug actually  
3 does its job. And when it's contaminated with --

4                   THE COURT: But that's not what this case is about.

5                   MS. GOLDENBERG: Well, as a personal injury lawyer  
6 that's not what my case is about, but on the class action  
7 side, I think we are going to see that defense.

8                   THE COURT: In terms of discovery, this case isn't  
9 about the health effects of taking uncontaminated Valsartan,  
10 is it? That's what you want.

11                  MS. GOLDENBERG: We want uncontaminated Valsartan,  
12 absolutely.

13                  THE COURT: No, no, no. You want discovery regarding  
14 the health effects of uncontaminated Valsartan.

15                  MS. GOLDENBERG: We want discovery about the health  
16 effects of contaminated Valsartan.

17                  THE COURT: Yes, I understand -- that, I understand.

18                  MS. GOLDENBERG: Sure.

19                  THE COURT: What else do you want?

20                  MS. GOLDENBERG: Adverse health effects about cancer,  
21 anything the defendants asked about in the plaintiff fact  
22 sheet, precancerous tumors or mutagenic diseases or disorders,  
23 and then anything relating to injuries to the digestive system  
24 that's implicated by taking Valsartan.

25                  THE COURT: Whether or not it's contaminated.

1 MS. GOLDENBERG: Yes.

2 THE COURT: Okay. I don't think I need to hear from  
3 the defendants. Any other issues we need to address before  
4 lunch? Okay -- one more.

5 MR. PAREKH: Sorry. One item is just in their issue  
6 No. 8. The submission by defendants is not quite right and I  
7 just want to make sure that we have the agreement that we've  
8 actually reached on the record, which is the agreement  
9 regarding the translation of foreign language documents, is  
10 that -- and you can correct me if I'm wrong, but it's our  
11 understanding that any translations that were created by  
12 defendants for reasons other than this litigation, that is,  
13 translations created during the normal course of business will  
14 be provided to us with the translated document. It's only  
15 translations that were created for purposes of this litigation  
16 that will be withheld.

17 THE COURT: I think that's fair.

18 So let me see if I can put that down in language,  
19 because I think that's important to be documented.  
20 Translations in the -- translations not specifically done just  
21 for this litigation?

22 MR. PAREKH: Correct, Your Honor.

23 THE COURT: Okay. I would assume, I don't know, that  
24 when they made submissions to the FDA, they had to be in  
25 English?

1 MR. PAREKH: Yes, there's definitely translated  
2 documents.

3 THE COURT: So someone translated Chinese too.

4 MR. PAREKH: Absolutely. And we just want to make  
5 sure that there's no miscommunication as to what is and isn't  
6 produced.

7 THE COURT: Okay. Any problem with that, defendants?

8 MR. GOLDBERG: No, You Honor. We have agreed any  
9 documents that have been translated in the normal course of  
10 business will been produced and they have been.

11 THE COURT: Okay. So we'll be back here at  
12 2 o'clock, you'll get the Court's rulings and then we will  
13 meet with Judge Kugler. Unless something unforeseen happens,  
14 I don't foresee that meeting with Judge Kugler being very  
15 long, but I asked Judge Kugler to be available, because, you  
16 know, frankly, you haven't seen Judge Kugler for a couple of  
17 our last meetings and maybe there's issues you want to address  
18 with him, so you'll have your opportunity to do that.

19 Thank you. We're adjourned.

20 THE DEPUTY CLERK: All rise.

21 (12:57 p.m.)

22 -

23 I certify that the foregoing is a correct transcript  
24 from the record of proceedings in the above-entitled matter.

25 /S/ Karen Friedlander, CRR, RMR  
Court Reporter/Transcriber 11-22-19/Date

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